

US3602030 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:09:20

All time stamps listed in this document are displayed in GMT

US3602030

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:08:09

Generated On: 10 Jun 2021 09:09:20

[Participant ID](#)

US3602030

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

US3602030

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 SEP 2020

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

Folder OID SCRN

US3602030

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	True
Not reported	False

US3602030

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Date of Informed Consent (*dd MMM yyyy*) 11 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

US3602030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Did the participant meet all eligibility criteria?

Yes

No

US3602030

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Were any significant conditions reported?

Yes

No

US3602030

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602030

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602030

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	DRY EYE SYNDROME
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602030

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	HAIR THINNING
Start date (dd MMM yyyy)	11 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602030

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602030

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	NON-ALLERGIC RHINITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3602030

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	ENDOMETRIOSIS S/P STRIPPING
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3602030

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	TOOTH CLEANING
Start date (dd MMM yyyy)	6 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	6 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3602030

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	ROOT CANAL
Start date (dd MMM yyyy)	28 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3602030

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Condition	MULTIPLE SINUS SURGERIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3602030

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 11 SEP 2020

Time of assessment (*00:00-23:59*) 09:12 (24 HR)

Vital Signs Date and Time (derived) 11 SEP 2020 09:12

Height (*xxx.x*) 63 in

Weight (*xxx.x*) 218 lb

BMI (*xxx.x*) 38.69771 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3602030

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3602030

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*) 11 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*) _____

Date of last menstruation unknown False

US3602030

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 11 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3602030

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

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

ADMIN, NOT EXPOSED TO PEOPLE, REMOTE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3602030

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113375

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

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:12 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:12
Temperature (<i>xxx.x</i>)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:00 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:00
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

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.

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 11:30

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

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:12 (24 HR)
Collection date and time (derived)	11 SEP 2020 09:12

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:03:27

Generated On: 10 Jun 2021 09:09:20

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	11 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

US3602030

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 11 SEP 2020 12:02
PC Open Date & Time 11 SEP 2020 11:50
PC Close Date & Time 11 SEP 2020 14:20

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 97.3 °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 11 SEP 2020 19:21
PC Open Date & Time 11 SEP 2020 15:15
PC Close Date & Time 12 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 14:10
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 13:21
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 12:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 13:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 12:15
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 12:24
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 11:50

PC Close Date & Time

11 SEP 2020 14:20

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

11 SEP 2020 19:21

PC Open Date & Time

11 SEP 2020 15:15

PC Close Date & Time

12 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 SEP 2020 14:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 13:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 SEP 2020 12:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	15 SEP 2020 13:20
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

16 SEP 2020 12:16

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 12:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

No
Yes

PC Time stamp	11 SEP 2020 12:03
PC Open Date & Time	11 SEP 2020 11:50
PC Close Date & Time	11 SEP 2020 14:20

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

No

Yes

PC Time stamp	11 SEP 2020 19:22
PC Open Date & Time	11 SEP 2020 15:15
PC Close Date & Time	12 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 14:10
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 13:21
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 12:42
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 13:19
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 12:16
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 12:25
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 19 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 16 OCT 2020

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

Folder OID VISIT2

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:55 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:55
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:06 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:06
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 16 OCT 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

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 OCT 2020

What was the treatment time? (00:00-23:59) 10:36 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 10:36

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

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:06 (24 HR)
Collection date and time (derived)	16 OCT 2020 09:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Collection date (<i>dd MMM yyyy</i>)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:06	16 OCT 2020 09:06
Nasopharyngeal Swab 2	No		

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 97.9 °F

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

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

PC Time Stamp 16 OCT 2020 11:10

PC Open Date & Time 16 OCT 2020 10:56

PC Close Date & Time 16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 98.8 °F

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

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

PC Time Stamp 16 OCT 2020 18:33
PC Open Date & Time 16 OCT 2020 14:21
PC Close Date & Time 17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 OCT 2020 15:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 OCT 2020 14:14
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 OCT 2020 15:17
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 OCT 2020 12:09
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 OCT 2020 14:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 OCT 2020 14:06
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 OCT 2020 11:11

PC Open Date & Time

16 OCT 2020 10:56

PC Close Date & Time

16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 OCT 2020 18:34

PC Open Date & Time

16 OCT 2020 14:21

PC Close Date & Time

17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 OCT 2020 15:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 OCT 2020 14:14

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 OCT 2020 15:18

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	20 OCT 2020 12:08
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	21 OCT 2020 14:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 OCT 2020 14:06

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

No

Yes

PC Time stamp	16 OCT 2020 11:11
PC Open Date & Time	16 OCT 2020 10:56
PC Close Date & Time	16 OCT 2020 13:26

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

No

Yes

PC Time stamp	16 OCT 2020 18:35
PC Open Date & Time	16 OCT 2020 14:21
PC Close Date & Time	17 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	17 OCT 2020 15:41
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 14:15
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	19 OCT 2020 15:18
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 12:08
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 14:03
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

	Yes <input type="checkbox"/>
PC Time stamp	22 OCT 2020 14:06
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:03:26

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 NOV 2020

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

Folder OID VISIT3

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 09:25
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:25 (24 HR)
Collection date and time (derived)	13 NOV 2020 09:25

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:29:45

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 19 NOV 2020 09:35:40

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 75

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 22 NOV 2020 09:16:29

Patient Cloud Open Date & Time 22 NOV 2020 00:01

Patient Cloud Close Date & Time 26 NOV 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 82

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 29 NOV 2020 00:06:56

Patient Cloud Open Date & Time 29 NOV 2020 00:01

Patient Cloud Close Date & Time 03 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 89

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 06 DEC 2020 00:06:31

Patient Cloud Open Date & Time 06 DEC 2020 00:01

Patient Cloud Close Date & Time 10 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 13:25:23
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 14:39:41
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 12:14:00
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 08:26:30
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 07:09:16
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 17 JAN 2021 03:41:57

Patient Cloud Open Date & Time 17 JAN 2021 00:01

Patient Cloud Close Date & Time 21 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 JAN 2021 17:29:00
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 22:00:49
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 07 FEB 2021 09:00:26

Patient Cloud Open Date & Time 07 FEB 2021 00:01

Patient Cloud Close Date & Time 11 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 07:52:36
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 07:31:01
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 11:46:29
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 08:31:06
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 13:48:30
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 22:10:17
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 12:14:26
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 04 APR 2021 17:30:23

Patient Cloud Open Date & Time 04 APR 2021 00:01

Patient Cloud Close Date & Time 08 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 08:40:08
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 08:21:08
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 17:58:07
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 02 MAY 2021 11:19:08

Patient Cloud Open Date & Time 02 MAY 2021 00:01

Patient Cloud Close Date & Time 06 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	23 MAY 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 24 JUN 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 320

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	01 AUG 2021 00:01
Patient Cloud Close Date & Time	05 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 341

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 404

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 460

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	02 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	16 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	01 MAY 2022 00:01
Patient Cloud Close Date & Time	05 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#) 19 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)
- Chills
- Cough
- Shortness of breath
- Difficulty breathing
- Fatigue
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	28 AUG 2022 00:01
Patient Cloud Close Date & Time	01 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#) 18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 22 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3602030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:09:20

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
No		28 FEB 2021 11:46:43

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments OL- VISIT 2 D 29 AND PART -A D
149 SAFETY CALL (2/13/2021 -/+
3) OVERLAPPED AND WERE
COMBINED. ALL ASSESSMENTS
AND PROCEDURES WERE
COMPLETED AS PER
PROTOCOL ON 11/FEB/2021..

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 01:12:01

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 16 APR 2021

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

Folder OID VISIT4

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 01:12:01

Generated On: 10 Jun 2021 09:09:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 APR 2021
Time of assessment (<i>00:00-23:59</i>)	08:30 (24 HR)
Vital Signs Date and Time (derived)	16 APR 2021 08:30
Temperature (<i>xxx.x</i>)	96.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 01:12:01

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

16 APR 2021

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

US3602030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 16 APR 2021

Collection time (*00:00-23:59*) 08:40 (24 HR)

Collection date and time (derived) 16 APR 2021 08:40

US3602030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

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

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

Comments _____

If Contact Not Made, please provide Comments _____

US3602030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3602030

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 JAN 2021

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

Folder OID UNBLND_DECIDE

US3602030

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3602030

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3602030

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 09:10
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 11:25
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3602030

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

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 15 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3602030

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 10:40

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

US3602030

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 JAN 2021

Collection time (*00:00-23:59*) 09:45 (24 HR)

Collection date and time (derived) 15 JAN 2021 09:45

US3602030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 JAN 2021
Collection time (<i>00:00 - 23:59</i>)	08:40
Collection Date and Time (derived)	15 JAN 2021 08:40

US3602030

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:21

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3602030

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 FEB 2021

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

Folder OID OLD29

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:21 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:21
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:31 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 10:31
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3602030

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 11 FEB 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3602030

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 10:01 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 10:01

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

US3602030

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:59:25

Generated On: 10 Jun 2021 09:09:20

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3602030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3602030

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 MAR 2021

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

Folder OID OLD57

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:20 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:20
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3602030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 MAR 2021
Collection time (<i>00:00-23:59</i>)	08:55 (24 HR)
Collection date and time (derived)	11 MAR 2021 08:55

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 05 Apr 2021 20:59:25

Generated On: 10 Jun 2021 09:09:20

Visit Date	22 SEP 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3602030

Folder: Unscheduled 22 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:59:25

Generated On: 10 Jun 2021 09:09:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:52 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 08:52
Temperature (<i>xxx.x</i>)	96.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Physical Examination**

Data signed: (b) (4) 05 Apr 2021 20:59:25

Generated On: 10 Jun 2021 09:09:20

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3602030

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:08:10

Generated On: 10 Jun 2021 09:09:20

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event SWELLING TO THE RIGHT SIDE
OF THE FACE

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) 17 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 27 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 361 of 2977
EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

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 False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

PT HAD HER IP ON SEP 11TH

HAD HER TOOTH CLEANING
AND ROOT CANAL DONE AUG
6TH AND AUGUST 28TH AND
WAS WELL PRIOR TO THE
VACCINE
PMHX OF SINUS SURGERIES IN
THE PAST

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH

OVER THE NEXT 24HR HAD
INCREASING TINGLING AND
NUMBNESS ALONG THE JAW
LINE AND INCREASING
SWELLING AND FULLNESS
OVER THE MAXILLA
NO NASAL DISCHARGE
THE PAIN PERSISTED ON THE
WEEKEND AND SHE SAW HER
DENTIST ON 9/21 AND CALLED
ME FROM THERE SINCE THE
DENTIST DID NOT FIND ANY
ISSUES WITH THE TOOTH AND
FELT THAT IT COULD BE
SHINGLES AND OF

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

SOME OTHER MEDICAL ISSUES
LEADING TO REFERRED PAIN

ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

REC : SEEK EVAL BY ENT AND
OR MEDICAL DOCTOR
HAVE THE DENTIST AND THE
OTHER PHYSICIANS SHE SEES
TO FAX THE RECORDS TO US

(b) (6)

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)	0

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event ANXIETY RELATED TO THE
VACCINE

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) 17 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 7 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

PRODUCTION RELEASE (v12.003 365 of 2977
EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH
ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

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

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event TINGLING ON RIGHT SIDE OF
FACE

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) 17 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 28 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 368 of 2977
EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

PT HAD HER IP ON SEP 11TH

HAD HER TOOTH CLEANING
AND ROOT CANAL DONE AUG
6TH AND AUGUST 28TH AND
WAS WELL PRIOR TO THE
VACCINE
PMHX OF SINUS SURGERIES IN
THE PAST

NO ISSUES RELATED TOT HE
VACCINE ITSELF BUT THEN ON
THURSDAY STARTED WITH
PAIN ON CHEWING IN THE
BACK TEETH AND THOUGHT
WAS RELATED TO THE ROOT
CANAL AND NEVER
MENTIONED IT ON THE SAFETY
CALL WITH ME ON FRIDAY THE
18TH

OVER THE NEXT 24HR HAD
INCREASING TINGLING AND
NUMBNESS ALONG THE JAW
LINE AND INCREASING
SWELLING AND FULLNESS
OVER THE MAXILLA
NO NASAL DISCHARGE
THE PAIN PERSISTED ON THE
WEEKEND AND SHE SAW HER
DENTIST ON 9/21 AND CALLED
ME FROM THERE SINCE THE
DENTIST DID NOT FIND ANY
ISSUES WITH THE TOOTH AND
FELT THAT IT COULD BE
SHINGLES AND OF

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

SOME OTHER MEDICAL ISSUES
LEADING TO REFERRED PAIN

ON TODAY'S LIMITED EXAM:
VITALS : 96.4 , 128/81, PLSE OX
100% HR 98 RR 12
BMI 38.4
SHE DOES HAVE SWELLING TO
THE CHEEK AND JAW AREA
NO REDNESS TO THE FACE
NO TOOTH DECAY NOTED , NO
PAIN ON PALPATION OF THE
TOOTH
NO SWELLING OF THE JAW
NO FACIAL DROOP
NO NASAL CONGESTION OR
REDNESS

REC : SEEK EVAL BY ENT AND
OR MEDICAL DOCTOR
HAVE THE DENTIST AND THE
OTHER PHYSICIANS SHE SEES
TO FAX THE RECORDS TO US

(b) (6)

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event LEFT SIDED PLEURITIC CHEST
PAIN

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) 27 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 29 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 372 of 2977
EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

L SIDED BACK / THORACIC CHEST PAIN SO SHE WENT TO HER PCP ON 9/28 AND HAD AN EKG DONE WHICH WAS NORMAL . SHE HAD LABS DONE TODAY (NL) AND HAD A CXR DONE WHICH WAS ALSO NORMAL . . NO MEDS AND NO OTC TAKE THUS FAR . WAS SENT TO THE CARDIOLOGIST (b) (6) , WHOM SHE SAW TODAY 10/7 AND HAD EVALUATION DONE . HE DID NOT THINK IT IS CARDIAC IN ORIGIN BUT REC ECHO (10/9) AND STRESS TEST ON (10/13)

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event LEFT SIDED CHEST WALL
WARMTH

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) 6 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) 16 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

PRODUCTION RELEASE (v12.003 375 of 2977
EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity True

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 False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

WILL NOT BE PURSUING THE
SECOND DOSE OF THE
INVESTIGATIONAL PRODUCT
STARTED WITH CHEST WALL
PAIN AND TINGLING AND
FEELING OF WARMTH TO THE
SIDE THAT STARTED
YESTERDAY EVENING WHILE
LYING DOWN AND
MENTIONED IT TO THE
CARDIOLOGIST TOO . SHE HAS
BEEN RECOMMENDED TO
HAVE THE NEUROLOGIST
ASSESS HER FOR ANY
ETIOLOGY FOR THE
SYMPTOMS
PT IS GOING TO BE MAKING AN
APPT AND WILL LET US KNOW
THE OUTCOME

SHE DOES ASK ME TO UN
BLIND HER FROM THE STUDY
GIVEN VARIOUS SYMPTOMS
WITH NO DIAGNOSIS MADE
AND CONCERN FOR VACCINE
RELATED ISSUES

I HAVE HAD THE DISCUSSION
WITH (b) (6) REG THE
SAME

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID USA-US079-2020-MRNA-1273-P30
1000001

Adverse event LEFT SIDED TINGLING

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) 6 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) 16 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

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU _____

Persistent or significant disability or incapacity True

Congenital anomaly or birth defect False

Other medically important event True

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 False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

STARTED WITH CHEST WALL
PAIN AND TINGLING AND
FEELING OF WARMTH TO THE
SIDE THAT STARTED
YESTERDAY EVENING WHILE
LYING DOWN AND
MENTIONED IT TO THE
CARDIOLOGIST TOO . SHE HAS
BEEN RECOMMENDED TO
HAVE THE NEUROLOGIST
ASSESS HER FOR ANY
ETIOLOGY FOR THE
SYMPTOMS
PT IS GOING TO BE MAKING AN
APPT AND WILL LET US KNOW
THE OUTCOME

SHE DOES ASK ME TO UN
BLIND HER FROM THE STUDY
GIVEN VARIOUS SYMPTOMS
WITH NO DIAGNOSIS MADE
AND CONCERN FOR VACCINE
RELATED ISSUES

I HAVE HAD THE DISCUSSION
WITH (b) (6) REG THE
SAME

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)	

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	18 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	24 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2977

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

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)

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID

Adverse event

MIGRAINE HEADACHE

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 NOV 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 NOV 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

PRODUCTION RELEASE (v12.003

383 of 2977

EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID

Adverse event

MIGRAINE HEADACHE

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)

02 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

03 NOV 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

PRODUCTION RELEASE (v12.003

385 of 2977

EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

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

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID

Adverse event

RIGHT MAXILLARY SINUS PAIN

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 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

17 FEB 2021

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

PRODUCTION RELEASE (v12.003

387 of 2977

EAB) (1725)

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID	
Adverse event	RIGHT TOOTH ACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2977

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID	
Adverse event	POST-NASAL DRIP CAUSING PHARYNGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

AEID	
Adverse event	RIGHT MAXILLARY SINUS CONGESTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

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

Yes

No

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication NEXPLANON

Prophylaxis Yes
No

Indication CONTRACEPTION AND
ENDOMETRIOSIS

Dose per administration N/A

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify N/A

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 Q 3YEARS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify	INTRADERMAL
Start date (dd MMM yyyy)	24 JUN 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy)	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input type="radio"/>

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication ADVAIR

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 250/50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2004

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication TELMISARTAN

Prophylaxis Yes
No

Indication HTN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2012

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication RESTASIS 0.5 MG/ML

Prophylaxis Yes
No

Indication DRY EYE

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify GTTS

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)

402 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify OPHTHALMIC

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication ASTELIN 0.15%

Prophylaxis Yes
No

Indication NON- ALLERGIC RHINITIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2005

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication NEXIUM

Prophylaxis Yes
No

Indication ACID REFLUX

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication FLONASE 50MCG

Prophylaxis Yes
No

Indication NON- ALLERGIC RHINITIS

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)

408 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication DICLOFENAC

Prophylaxis Yes
No

Indication LEFT KNEE OA

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 3

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

2X A WEEK

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication GOOD HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication BIOTIN

Prophylaxis Yes
No

Indication THINNING OF HAIR

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN AUG 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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication VITAMIN D

Prophylaxis Yes
No

Indication MAINTAIN GOOD LEVEL

Dose per administration 2000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication PROBIOTIC

Prophylaxis Yes
No

Indication GOOD GI HEALTH

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____

Start date completely unknown True

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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 500

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)

422 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 18 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 18 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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication EXCEDRIN MIGRAINE
(ACETAMINOPHEN/ASPIRIN/
CAFFIENE)

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 250/250/65

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 23 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication EXCEDRIN (ACETAMINOPHEN /ASPIRIN/CAFFEINE)

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 500/500/130

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 02 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 02 NOV 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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication EXCEDRIN(
ACETAMINOPHEN/ASPIRIN/CAF
FEINE)

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 500/500/130

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 04 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 04 NOV 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

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication KEFLEX

Prophylaxis Yes
No

Indication RIGHT MAXILLARY SINUS
PAIN/CONGESTION

Dose per administration 500

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	04 FEB 2021
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021
--	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	2
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Name of Medication KEFLEX

Prophylaxis Yes
No

Indication POST-NASAL DRIP CAUSING
PHARYNGITIS

Dose per administration 500

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Apr 2021 01:12:00

Generated On: 10 Jun 2021 09:09:20

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	7 APR 2021
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	16 APR 2021
--	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	2
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 20:59:24

Generated On: 10 Jun 2021 09:09:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	DENTIST VISIT	Adverse Event	
07 OCT 2020	EKG	Adverse Event	
07 OCT 2020	STRESS TEST	Adverse Event	
07 OCT 2020	CHEST X-RAY (CXR)	Adverse Event	

US3602030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:09:20

Date of dosing discontinuation (dd MMM yyyy)

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

US3602030

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:09:20

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

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/SEP/2020 07:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	_____
Site Address: City	_____
Site Address: State	NJ
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/OCT/2020 12:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	_____
Site Address: City	_____
Site Address: State	NJ
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/OCT/2020 12:31
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/OCT/2020 15:33
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.	<input checked="" type="checkbox"/> True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	_____
Site Address: City	_____
Site Address: State	NJ
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/OCT/2020 09:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	_____
Site Address: City	_____
Site Address: State	NJ
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 08:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	_____
Site Address: City	_____
Site Address: State	NJ
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:36
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

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Feb 2021 22:08:11

Generated On: 10 Jun 2021 09:09:20

SAEID	USA-US079-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/NOV/2020 19:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

Audit

US3602030 (Prod: Hackensack University Medical Center)

US3602030

Form: Participant Creation

Generated On: 10 Jun 2021 09:09:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'US3602030'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:25

US3602030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:26

US3602030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'SCRN'	System	11 Sep 2020 14:26:17

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:27

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '41'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'YEARS'	System	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '41'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:20

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:37

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Sep 2020'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:26:54

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

If Yes, [previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:26

US3602030

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '1'	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:09:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:31:07
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 15:57:41

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:36:35
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'not all asthma requires treatment. personally I am not being treated for asthma currently. subject may be stable at the time being and does not require baseline treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 17:35:45
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:56:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:36
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Asthma'	(b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 1995'	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '1995'	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:33:52

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:37
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Hypertension'	(b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 2014'	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2014'	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:12

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:46
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:35:53
Data point term sent to Coder	System	16 Sep 2020 14:34:44
User entered 'Dry Eye Syndrome'	(b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 2012'	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2012'	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:30

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:42
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:45
User entered 'Acid Reflux'	(b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 2010'	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2010'	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:34:53

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair thinning - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:48
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair thinning - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:47
User entered 'Hair Thinning'	(b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Aug 2020'	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:08

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:48
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:36:40
Data point term sent to Coder	System	16 Sep 2020 14:35:48
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 2015'	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2015'	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:21

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 21:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 21:03:48
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	16 Sep 2020 14:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:37:08
Data point term sent to Coder	(b) (4)	16 Sep 2020 14:35:47
User entered 'Insomnia'	System	16 Sep 2020 14:35:43
	(b) (4), (b) (6)	

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Jan 2010'	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2010'	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:35:43

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:45
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User closed query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:39:36
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:55:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:55:32
Data point term sent to Coder	System	21 Oct 2020 17:54:47
Query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 17:54:29
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 17:54:19
User entered 'Vitamin D Insufficiency' reason for change: Per Query Resolution	(b) (4), (b) (6)	21 Oct 2020 17:54:19

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:57:50
User coded data point as SOC: Investigations, HLG: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
Data point term sent to Coder	System	16 Sep 2020 14:36:48
User entered 'Low Vitamin D'	(b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:36:46

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:41
Data point term sent to Coder	System	15 Feb 2021 21:03:28
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:49
Data point term sent to Coder	System	16 Sep 2020 14:37:49
User entered 'Left Knee Osteoarthritis'	(b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:04

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
Data point term sent to Coder	System	15 Feb 2021 21:03:30
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:38:47
Data point term sent to Coder	System	16 Sep 2020 14:37:52
User entered 'Non-Allergic Rhinitis'	(b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:21

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:47
Data point term sent to Coder	System	15 Feb 2021 21:03:30
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:00:52
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 09:00:52
Data point term sent to Coder	System	16 Sep 2020 14:37:52
User entered 'Endometriosis s/p Stripping'	(b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	16 Sep 2020 14:37:38

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Dental cleaning, LLT: Dental cleaning - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:46
Data point term sent to Coder	System	15 Feb 2021 21:03:31
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Dental cleaning, LLT: Dental cleaning - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:53:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:53:09
Data point term sent to Coder	System	15 Oct 2020 13:21:29
User entered 'Tooth Cleaning'	(b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '6 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '6 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Aug 2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Aug 2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	15 Oct 2020 13:20:47

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Endodontic procedure, LLT: Root canal procedure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 21:03:42
Data point term sent to Coder	System	15 Feb 2021 21:03:31
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
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) (4), (b) (6)	29 Oct 2020 06:23:30
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 'doesnt say why subject had a root canal, simply states subject had root canal and teeth cleaning on 8/6/2020' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:35:17
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)	27 Oct 2020 05:57:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Endodontic procedure, LLT: Root canal procedure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 13:22:28
Data point term sent to Coder	System	15 Oct 2020 13:21:30
User entered 'Root Canal'	(b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Aug 2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'Aug 2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '2020'	System	15 Oct 2020 13:21:13

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:18:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:18:41
Data point term sent to Coder	System	15 Feb 2021 21:03:31
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 21:03:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:10:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:10:29
Data point term sent to Coder	System	09 Nov 2020 16:36:08
User entered 'Multiple Sinus Surgeries'	(b) (4), (b) (6) (b) (4)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	09 Nov 2020 16:35:55

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '09:12'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '63' in reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:17:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '218' lb reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:17:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '38.69771'	System	14 Sep 2020 18:17:08
User entered empty.	System	14 Sep 2020 13:55:59
User entered '38.69771'	System	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'kg/m2'	System	14 Sep 2020 18:17:08
User entered empty.	System	14 Sep 2020 13:55:59
User entered 'kg/m2'	System	11 Sep 2020 16:08:12
DataPoint set to visible.	System	11 Sep 2020 14:27:03

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '96.7' F	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '62'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'bpm'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'breaths/min'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '113'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 13:55:59
User entered '70'	(b) (4), (b) (6)	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	11 Sep 2020 16:08:12

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54

US3602030

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54

US3602030

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:59:50

US3602030

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:59:50

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	(b) (4)	14 Sep 2020 13:56:56
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	11 Sep 2020 16:06:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:56:56
User entered 'UN UNK 2020'	(b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:09:20

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:06:54

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	11 Sep 2020 16:08:25

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Admin, not exposed to people, remote'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:19

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'VISIT1'	System	11 Sep 2020 16:04:29

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '113375'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:54:49

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:05:12

US3602030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:03:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:07:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:33

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:12'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.		15 Feb 2021 22:29:45
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).		21 Sep 2020 10:33:04
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 'This is NCS per the provider' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 12:55:18
Amendment Manager: 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	17 Sep 2020 00:33:06
User entered '96.7' F	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '62'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'bpm'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'breaths/min'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '113'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '70'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '63' in	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:48
User entered '218' lb	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '12:00'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '67'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'bpm'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'breaths/min'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '129'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	11 Sep 2020 16:10:18

US3602030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:04:38

US3602030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:16:22
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:04:38

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User closed query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:07:04
Query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:11:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 13:11:06
User opened query 'Per CDM: Re-query: Since, subject is screened, enrolled, randomized, and dose on the same day, please update this data point as NO.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:33:55
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:33:55
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:32:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 12:54:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED] [REDACTED]	16 Sep 2020 11:11:18
	(b) (4), (b) (6) [REDACTED]	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	15 Feb 2021 22:29:45
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 13:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4)	25 Sep 2020 13:10:26
Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:10:26
Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:08:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:08:34
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 08:19:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 13:11:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 12:54:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 14:53:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered empty.	System	11 Sep 2020 16:10:30

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11:30'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '11 Sep 2020 11:30'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'ONCE'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 16:00:13

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:12'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:45

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '09:12'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered empty.	System	11 Sep 2020 16:10:59

US3602030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:11:05

US3602030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	11 Sep 2020 16:11:05

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered 'Yes (Y)'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered '98.6'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd'	System	11 Sep 2020 16:05:38
User entered 'No (N)'	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1efc487e-1e5f-4233-a6d2-f9fc1c6789cd' User entered '11 Sep 2020 12:02'	System	11 Sep 2020 16:05:38
	System	11 Sep 2020 16:05:38

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered 'Yes (Y)'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered '97.3'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered 'No (N)'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ecfd982-9efd-4c4c-bee6-daed648b8759'	System	11 Sep 2020 23:21:13
User entered '11 Sep 2020 19:21'	System	11 Sep 2020 23:21:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered 'Yes (Y)'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:33', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered '98.2'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered 'No (N)'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6528f49-a2ee-426d-a772-0fae8f4f04d2'	System	12 Sep 2020 18:10:41
User entered '12 Sep 2020 14:10'	System	12 Sep 2020 18:10:41

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered 'Yes (Y)'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:03', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered '98.2'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered 'No (N)'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9629adeb-42da-455a-b7c0-d208f4d63a45'	System	13 Sep 2020 17:21:16
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:21:16

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered 'Yes (Y)'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:15', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered '98.5'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered 'No (N)'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9201c8f6-bfd5-4634-81bb-652af2554451'	System	14 Sep 2020 16:41:39
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 16:41:39

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered 'Yes (Y)'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered '98.3'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:11', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered 'No (N)'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:21:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0a3ba6da-50f1-43f1-99ca-354dfad0fd22'	System	15 Sep 2020 17:21:15
User entered '15 Sep 2020 13:21'	System	15 Sep 2020 17:21:15

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered 'Yes (Y)'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered '98.4'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered 'No (N)'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e2f4fc87-3452-4491-a83a-67b40f18752a'	System	16 Sep 2020 16:15:56
User entered '16 Sep 2020 12:15'	System	16 Sep 2020 16:15:56

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered 'Yes (Y)'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered '98.6'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered 'No (N)'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4aa8669d-3bb8-43e1-91df-ecfbb6cef837'	System	17 Sep 2020 16:24:37
User entered '17 Sep 2020 12:24'	System	17 Sep 2020 16:24:37

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:02:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'None (1)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'No (N)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:17', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'No (N)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered 'None (1)'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b4e8a0e6-fb2a-4688-9fbc-ad326c6059cc'	System	11 Sep 2020 16:06:24
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:24

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'None (1)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'No (N)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'No (N)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered 'None (1)'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1c629fa9-8c02-403a-83df-2e00c3ce830c'	System	11 Sep 2020 23:21:46
User entered '11 Sep 2020 19:21'	System	11 Sep 2020 23:21:46

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'None (1)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'No (N)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'No (N)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered 'None (1)'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2abea7fa-fe70-4b3c-a34f-deb0302a182e'	System	12 Sep 2020 18:09:47
User entered '12 Sep 2020 14:09'	System	12 Sep 2020 18:09:47

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'None (1)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'No (N)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'No (N)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered 'None (1)'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9790e08b-9958-4f34-b879-6523acaaa47f'	System	13 Sep 2020 17:21:48
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:21:48

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'None (1)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'No (N)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'No (N)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered 'None (1)'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'dc1fa60c-a5dc-4607-a6d2-cb24e89880ea'	System	14 Sep 2020 16:41:50
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 16:41:50

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'None (1)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:27', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'No (N)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:33', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'No (N)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered 'None (1)'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:20:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '94fa49c7-2f90-4e88-8228-d034e609b3cf'	System	15 Sep 2020 17:20:54
User entered '15 Sep 2020 13:20'	System	15 Sep 2020 17:20:54

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:15:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'None (1)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'No (N)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'No (N)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered 'None (1)'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '8849661b-3712-4954-9b62-57124bccdf92'	System	16 Sep 2020 16:16:14
User entered '16 Sep 2020 12:16'	System	16 Sep 2020 16:16:14

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'None (1)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'No (N)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'No (N)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered 'None (1)'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4073ab8d-6047-4d37-b750-889b39e3ed78'	System	17 Sep 2020 16:24:57
User entered '17 Sep 2020 12:24'	System	17 Sep 2020 16:24:57

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:37', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'None (0)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered 'No (N)'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T12:03:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4ceaa4dc-175a-4bb1-8376-11d2991b2728'	System	11 Sep 2020 16:06:42
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 16:06:42

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 11:50'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:21:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'None (0)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:22:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered 'No (N)'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-11T19:22:05', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'a716633b-e56d-4619-9416-b48618a906e0'	System	11 Sep 2020 23:22:09
User entered '11 Sep 2020 19:22'	System	11 Sep 2020 23:22:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 2'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:09:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'None (0)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered 'No (N)'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-12T14:10:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '09af8554-05a3-4e11-8d4f-0b384eaaa7e3'	System	12 Sep 2020 18:10:09
User entered '12 Sep 2020 14:10'	System	12 Sep 2020 18:10:09

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 3'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'None (0)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered 'No (N)'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-13T13:21:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2bcae4b9-f404-47e9-8c43-0dfeaec39b21'	System	13 Sep 2020 17:22:11
User entered '13 Sep 2020 13:21'	System	13 Sep 2020 17:22:11

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 4'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:41:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'None (0)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:15', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered 'No (N)'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-14T12:42:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3fd72fc9-160a-469d-bde5-a3957aa8a7eb'	System	14 Sep 2020 16:42:18
User entered '14 Sep 2020 12:42'	System	14 Sep 2020 16:42:18

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 5'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'None (0)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered 'No (N)'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-15T13:19:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c806ae03-27c0-46db-89b3-6f509665d328'	System	15 Sep 2020 17:19:59
User entered '15 Sep 2020 13:19'	System	15 Sep 2020 17:19:59

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 6'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f' User entered 'None (0)'	System	16 Sep 2020 16:16:32
	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f' User entered 'None (0)'	System	16 Sep 2020 16:16:32
	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:23', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f' User entered 'None (0)'	System	16 Sep 2020 16:16:32
	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f'	System	16 Sep 2020 16:16:32
User entered 'None (0)'	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f' User entered 'No (N)'	System	16 Sep 2020 16:16:32
	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-16T12:16:31', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f00f4b0-460c-4994-861e-c8f922b5e32f' User entered '16 Sep 2020 12:16'	System	16 Sep 2020 16:16:32
	System	16 Sep 2020 16:16:32

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 7'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:24:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:03', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:05', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'None (0)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered 'No (N)'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-09-17T12:25:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7ab5609a-7431-441d-9fd1-192f0b7a6180'	System	17 Sep 2020 16:25:13
User entered '17 Sep 2020 12:25'	System	17 Sep 2020 16:25:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:13

US3602030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:16:02

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:16:06

US3602030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	22 Sep 2020 15:16:06

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:32

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:08

US3602030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	28 Sep 2020 17:57:08

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:49:32

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:49:35

US3602030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	05 Oct 2020 20:49:35

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'VISIT2'	System	16 Oct 2020 14:25:06

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '08:55'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '16 Oct 2020 08:55'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '70'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'bpm'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'breaths/min'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '114'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	16 Oct 2020 14:26:02

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of 29 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:15:09
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of 29 minutes. Please review and update or provide a clarification. Thank you' answered with 'correct time updated' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:24:50
User entered '11:06' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 19:24:42
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of 29 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 21:50:32
User entered '11:05'	(b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '16 Oct 2020 11:06'	System	01 Dec 2020 19:24:42
User entered '16 Oct 2020 11:05'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '67'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'bpm'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'breaths/min'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '104'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '77'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	18 Nov 2020 15:44:45

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:36

US3602030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:36

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered empty.	System	16 Oct 2020 14:26:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '10:36'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '16 Oct 2020 10:36'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'ONCE'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 14:38:44

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:06'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '16 Oct 2020 09:06'	System	16 Oct 2020 14:26:16

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:06'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '16 Oct 2020 09:06'	System	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered empty.	System	16 Oct 2020 14:26:27

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:26:30

US3602030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	16 Oct 2020 14:26:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered 'Yes (Y)'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered '97.9'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered 'No (N)'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '48fcc636-08e2-4821-ad7d-2a3724c61b42'	System	16 Oct 2020 15:10:30
User entered '16 Oct 2020 11:10'	System	16 Oct 2020 15:10:30

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered 'Yes (Y)'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered '98.8'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered 'No (N)'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'f10d8f6a-383f-41f9-8146-8612a973cb46'	System	16 Oct 2020 22:33:52
User entered '16 Oct 2020 18:33'	System	16 Oct 2020 22:33:52

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered 'Yes (Y)'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered '97.9'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered 'No (N)'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:40:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2428ac72-ef34-4f4b-8aee-ed873032b089'	System	17 Oct 2020 19:40:54
User entered '17 Oct 2020 15:40'	System	17 Oct 2020 19:40:54

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered 'Yes (Y)'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d' User entered '97.9'	System	18 Oct 2020 18:14:21
	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered 'No (N)'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92bb57e0-9981-416f-87ad-af0b324d464d'	System	18 Oct 2020 18:14:21
User entered '18 Oct 2020 14:14'	System	18 Oct 2020 18:14:21

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered 'Yes (Y)'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered '98.7'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered 'No (N)'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '590a2eb6-ec5f-4e5a-9fcc-c534a67c8b77'	System	19 Oct 2020 19:17:48
User entered '19 Oct 2020 15:17'	System	19 Oct 2020 19:17:48

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered 'Yes (Y)'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered '98.5'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered 'No (N)'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:09:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'aa06b645-b3f8-484c-8c12-9015a47b8923'	System	20 Oct 2020 16:09:15
User entered '20 Oct 2020 12:09'	System	20 Oct 2020 16:09:15

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered 'Yes (Y)'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered '98.6'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered 'No (N)'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72aa5e9f-c537-483c-9951-36deb6530a63'	System	21 Oct 2020 18:02:40
User entered '21 Oct 2020 14:02'	System	21 Oct 2020 18:02:40

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered 'Yes (Y)'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:11', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered '98.2'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered 'No (N)'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'ff41a982-7777-43d9-ad6a-a07ec3eff02b'	System	22 Oct 2020 18:06:25
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:25

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:35', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'None (1)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:10:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'No (N)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'No (N)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:27', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered 'None (1)'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '06f5acc5-09cd-444c-8230-a039b2068463'	System	16 Oct 2020 15:11:30
User entered '16 Oct 2020 11:11'	System	16 Oct 2020 15:11:30

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:33:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'None (1)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:18', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'No (N)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'No (N)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered 'None (1)'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '970037c8-a6d7-49b2-b50e-6a26f09de257'	System	16 Oct 2020 22:34:50
User entered '16 Oct 2020 18:34'	System	16 Oct 2020 22:34:50

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'None (1)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'No (N)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'No (N)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered 'None (1)'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:31', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'e6bf9855-c536-4b8f-bdb8-ae2d9a256866'	System	17 Oct 2020 19:41:31
User entered '17 Oct 2020 15:41'	System	17 Oct 2020 19:41:31

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'None (1)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'No (N)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'No (N)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered 'None (1)'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '89384f0c-0596-411c-999a-345e36fe54cb'	System	18 Oct 2020 18:14:54
User entered '18 Oct 2020 14:14'	System	18 Oct 2020 18:14:54

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'None (1)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'No (N)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'No (N)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:17:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered 'None (1)'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '92da914c-03c1-4065-8ba6-b78802b92422'	System	19 Oct 2020 19:18:05
User entered '19 Oct 2020 15:18'	System	19 Oct 2020 19:18:05

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:07:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'None (1)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'No (N)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'No (N)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered 'None (1)'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:17', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7f709013-1345-47df-be0a-8c975aadabd3'	System	20 Oct 2020 16:08:19
User entered '20 Oct 2020 12:08'	System	20 Oct 2020 16:08:19

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'None (1)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'No (N)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'No (N)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered 'None (1)'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:02:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '91c5b93f-fab0-4760-a241-4bb5aa22083b'	System	21 Oct 2020 18:02:57
User entered '21 Oct 2020 14:02'	System	21 Oct 2020 18:02:57

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'None (1)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'No (N)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ed8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'No (N)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ede8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered 'None (1)'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '15563475-ede8-4b96-a99e-0fc2c90ed40a'	System	22 Oct 2020 18:06:40
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:40

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'None (0)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered 'No (N)'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T11:11:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'fc070be7-df65-464c-918e-3a2343a04118'	System	16 Oct 2020 15:11:53
User entered '16 Oct 2020 11:11'	System	16 Oct 2020 15:11:53

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 10:56'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 13:26'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:53', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:34:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'None (0)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered 'No (N)'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-16T18:35:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '74e4a625-a659-473a-ad65-b708187ca386'	System	16 Oct 2020 22:35:10
User entered '16 Oct 2020 18:35'	System	16 Oct 2020 22:35:10

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '16 Oct 2020 14:21'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 2'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:34', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'No interference with activity (1)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'None (0)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0'	System	17 Oct 2020 19:42:00
User entered 'No (N)'	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-17T15:41:59', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cdb5ed74-21f0-4909-afd9-7a5baaef9ab0' User entered '17 Oct 2020 15:41'	System	17 Oct 2020 19:42:00
	System	17 Oct 2020 19:42:00

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 3'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:14:58', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:02', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'None (0)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered 'No (N)'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-18T14:15:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bda2e95e-96e7-4746-99cd-e84c0ed3d4e1'	System	18 Oct 2020 18:15:13
User entered '18 Oct 2020 14:15'	System	18 Oct 2020 18:15:13

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 4'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:04', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'No interference with activity (1)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:06', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:09', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'None (0)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered 'No (N)'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-19T15:18:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '95484fbc-1657-4cc1-a4db-8c395dcf7b9a'	System	19 Oct 2020 19:18:21
User entered '19 Oct 2020 15:18'	System	19 Oct 2020 19:18:21

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 5'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:24', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:28', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:44', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'None (0)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:46', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered 'No (N)'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-20T12:08:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c8f4556a-2816-4fa0-a099-be65b6538b57'	System	20 Oct 2020 16:08:51
User entered '20 Oct 2020 12:08'	System	20 Oct 2020 16:08:51

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 6'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:07', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'No interference with activity (1)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:08', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:10', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:12', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:14', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'None (0)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered 'No (N)'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-21T14:03:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '9632983a-d7c0-4130-89d8-06e89b76d691'	System	21 Oct 2020 18:03:25
User entered '21 Oct 2020 14:03'	System	21 Oct 2020 18:03:25

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	16 Oct 2020 14:38:44
User entered 'Day 7'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:42', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:47', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'None (0)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

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 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered 'No (N)'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1d2179f9609c3ab2)', Time: '2020-10-22T14:06:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '840569c7-6906-4e37-ad18-5567d24fd5f2'	System	22 Oct 2020 18:06:55
User entered '22 Oct 2020 14:06'	System	22 Oct 2020 18:06:55

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:38:44

US3602030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:38:44

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:16

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:21

US3602030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	28 Oct 2020 04:58:21

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	09 Nov 2020 16:30:11
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Nov 2020 16:30:11
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 16:30:11
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 16:29:59
User entered '16 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:29:59

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:18

US3602030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'I'	System	09 Nov 2020 16:30:18

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:37

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 21:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:30:44

US3602030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	09 Nov 2020 16:30:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'VISIT3'	System	18 Nov 2020 15:17:44

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:25'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '13 Nov 2020 09:25'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '83'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'bpm'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '18'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'breaths/min'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '122'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '80'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered 'mmHg'	System	18 Nov 2020 15:18:59

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34

US3602030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:09

US3602030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:09

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered '09:25'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '13 Nov 2020 09:25'	System	18 Nov 2020 15:19:37

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:19:41

US3602030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	18 Nov 2020 15:19:41

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 64'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:32:12
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered 'Day 71'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:23', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered 'No (N)'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered 'No (N)'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-19T09:35:40', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '4e24a4a7-ef73-4383-b511-05396d217372'	System	19 Nov 2020 14:35:43
User entered '19 Nov 2020 09:35:40'	System	19 Nov 2020 14:35:43

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 16:00:13

US3602030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:33:53
Data entry locked.	System	11 Sep 2020 16:00:13
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 16:00:13

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f'	System	22 Nov 2020 14:16:32
User entered 'No (N)'	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f'	System	22 Nov 2020 14:16:32
User entered 'No (N)'	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-22T09:16:29', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '23cb8628-1a08-4a02-bac1-da37801ea20f'	System	22 Nov 2020 14:16:32
User entered '22 Nov 2020 09:16:29'	System	22 Nov 2020 14:16:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-29T00:06:48', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cf0ee7e4-b94f-46ba-a9db-b249696afa26'	System	29 Nov 2020 05:06:57
User entered 'No (N)'	System	29 Nov 2020 05:06:57

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-29T00:06:52', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cf0ee7e4-b94f-46ba-a9db-b249696afa26'	System	29 Nov 2020 05:06:57
User entered 'No (N)'	System	29 Nov 2020 05:06:57

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-11-29T00:06:56', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'cf0ee7e4-b94f-46ba-a9db-b249696afa26' User entered '29 Nov 2020 00:06:56'	System	29 Nov 2020 05:06:57
	System	29 Nov 2020 05:06:57

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-06T00:06:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1f43d521-36eb-4d53-aa89-0213063707e5'	System	06 Dec 2020 05:06:36
User entered 'No (N)'	System	06 Dec 2020 05:06:36

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-06T00:06:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1f43d521-36eb-4d53-aa89-0213063707e5'	System	06 Dec 2020 05:06:36
User entered 'No (N)'	System	06 Dec 2020 05:06:36

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-06T00:06:31', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '1f43d521-36eb-4d53-aa89-0213063707e5' User entered '06 Dec 2020 00:06:31'	System	06 Dec 2020 05:06:36
	System	06 Dec 2020 05:06:36

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-14T13:25:19', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72349fdc-8f7e-4ed5-babc-2ce05c8a3d40'	System	14 Dec 2020 18:25:25
User entered 'No (N)'	System	14 Dec 2020 18:25:25

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-14T13:25:21', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72349fdc-8f7e-4ed5-babc-2ce05c8a3d40'	System	14 Dec 2020 18:25:25
User entered 'No (N)'	System	14 Dec 2020 18:25:25

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-14T13:25:23', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '72349fdc-8f7e-4ed5-babc-2ce05c8a3d40'	System	14 Dec 2020 18:25:25
User entered '14 Dec 2020 13:25:23'	System	14 Dec 2020 18:25:25

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-21T14:27:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '5ffe7aa1-353f-44be-abc8-ac7c5834e1ed' User entered 'No (N)'	System	21 Dec 2020 19:39:51
	System	21 Dec 2020 19:39:51

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-21T14:32:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '5ffe7aa1-353f-44be-abc8-ac7c5834e1ed'	System	21 Dec 2020 19:39:51
User entered 'Yes (Y)'	System	21 Dec 2020 19:39:51

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-21T14:39:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '5ffe7aa1-353f-44be-abc8-ac7c5834e1ed'	System	21 Dec 2020 19:39:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 19:39:51

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-21T14:39:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '5ffe7aa1-353f-44be-abc8-ac7c5834e1ed' User entered '21 Dec 2020 14:39:41'	System	21 Dec 2020 19:39:51
	System	21 Dec 2020 19:39:51

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-29T12:13:50', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c6d302b5-10d9-4794-8454-bb6cf67f082b' User entered 'No (N)'	System	29 Dec 2020 17:14:06
	System	29 Dec 2020 17:14:06

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-29T12:13:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c6d302b5-10d9-4794-8454-bb6cf67f082b'	System	29 Dec 2020 17:14:06
User entered 'No (N)'	System	29 Dec 2020 17:14:06

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2020-12-29T12:14:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'c6d302b5-10d9-4794-8454-bb6cf67f082b'	System	29 Dec 2020 17:14:06
User entered '29 Dec 2020 12:14:00'	System	29 Dec 2020 17:14:06

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-04T08:26:25', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '525c218d-c325-484a-a27f-b1608e9111f6'	System	04 Jan 2021 13:26:32
User entered 'No (N)'	System	04 Jan 2021 13:26:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-04T08:26:27', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '525c218d-c325-484a-a27f-b1608e9111f6'	System	04 Jan 2021 13:26:32
User entered 'No (N)'	System	04 Jan 2021 13:26:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-04T08:26:30', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '525c218d-c325-484a-a27f-b1608e9111f6'	System	04 Jan 2021 13:26:32
User entered '04 Jan 2021 08:26:30'	System	04 Jan 2021 13:26:32

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-10T07:09:11', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'd2b392d0-dba8-4d94-843c-8fd9442f19ff'	System	10 Jan 2021 12:09:18
User entered 'No (N)'	System	10 Jan 2021 12:09:18

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-10T07:09:13', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'd2b392d0-dba8-4d94-843c-8fd9442f19ff'	System	10 Jan 2021 12:09:18
User entered 'No (N)'	System	10 Jan 2021 12:09:18

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-10T07:09:16', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'd2b392d0-dba8-4d94-843c-8fd9442f19ff'	System	10 Jan 2021 12:09:18
User entered '10 Jan 2021 07:09:16'	System	10 Jan 2021 12:09:18

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-17T03:41:51', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '42a73fbf-c4b7-4c38-82c7-5a1dadffb62a'	System	17 Jan 2021 08:42:02
User entered 'No (N)'	System	17 Jan 2021 08:42:02

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-17T03:41:55', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '42a73fbf-c4b7-4c38-82c7-5a1dadffb62a'	System	17 Jan 2021 08:42:02
User entered 'No (N)'	System	17 Jan 2021 08:42:02

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-17T03:41:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '42a73fbf-c4b7-4c38-82c7-5a1dadffb62a' User entered '17 Jan 2021 03:41:57'	System	17 Jan 2021 08:42:02
	System	17 Jan 2021 08:42:02

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:28:41', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered 'Yes (Y)'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:28:38', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered 'No (N)'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:28:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered 'No (N)'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:28:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered 'Yes (Y)'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:28:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-25T17:29:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6ece2677-e617-42b8-aa04-c38ab7221611'	System	25 Jan 2021 22:29:11
User entered '25 Jan 2021 17:29:00'	System	25 Jan 2021 22:29:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-31T22:00:43', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3384b59e-4e1c-4f97-b8f3-d390f4425255'	System	01 Feb 2021 03:01:14
User entered 'No (N)'	System	01 Feb 2021 03:01:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-31T22:00:45', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3384b59e-4e1c-4f97-b8f3-d390f4425255'	System	01 Feb 2021 03:01:14
User entered 'No (N)'	System	01 Feb 2021 03:01:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-01-31T22:00:49', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3384b59e-4e1c-4f97-b8f3-d390f4425255'	System	01 Feb 2021 03:01:14
User entered '31 Jan 2021 22:00:49'	System	01 Feb 2021 03:01:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-07T09:00:20', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7c0e345c-bdb9-4c15-a18e-6d95b81ab92a'	System	07 Feb 2021 14:00:29
User entered 'No (N)'	System	07 Feb 2021 14:00:29

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-07T09:00:22', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7c0e345c-bdb9-4c15-a18e-6d95b81ab92a'	System	07 Feb 2021 14:00:29
User entered 'No (N)'	System	07 Feb 2021 14:00:29

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-07T09:00:26', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '7c0e345c-bdb9-4c15-a18e-6d95b81ab92a' User entered '07 Feb 2021 09:00:26'	System	07 Feb 2021 14:00:29
	System	07 Feb 2021 14:00:29

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-14T07:52:32', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '573b58b2-299b-4b9b-837b-fd52df03d487'	System	14 Feb 2021 12:52:39
User entered 'No (N)'	System	14 Feb 2021 12:52:39

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-14T07:52:33', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '573b58b2-299b-4b9b-837b-fd52df03d487'	System	14 Feb 2021 12:52:39
User entered 'No (N)'	System	14 Feb 2021 12:52:39

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-14T07:52:36', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '573b58b2-299b-4b9b-837b-fd52df03d487'	System	14 Feb 2021 12:52:39
User entered '14 Feb 2021 07:52:36'	System	14 Feb 2021 12:52:39

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-23T07:30:54', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '356e175b-19d0-45e6-bce6-a24e10d185d8'	System	23 Feb 2021 12:31:04
User entered 'No (N)'	System	23 Feb 2021 12:31:04

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-23T07:30:57', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '356e175b-19d0-45e6-bce6-a24e10d185d8'	System	23 Feb 2021 12:31:04
User entered 'No (N)'	System	23 Feb 2021 12:31:04

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-23T07:31:01', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '356e175b-19d0-45e6-bce6-a24e10d185d8'	System	23 Feb 2021 12:31:04
User entered '23 Feb 2021 07:31:01'	System	23 Feb 2021 12:31:04

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-28T06:46:16-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0c236294-3e38-4401-aef9-18e0ef6d8bc9'	System	28 Feb 2021 11:46:33
User entered 'No (N)'	System	28 Feb 2021 11:46:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-28T06:46:19-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0c236294-3e38-4401-aef9-18e0ef6d8bc9'	System	28 Feb 2021 11:46:33
User entered 'No (N)'	System	28 Feb 2021 11:46:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-28T06:46:29-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '0c236294-3e38-4401-aef9-18e0ef6d8bc9'	System	28 Feb 2021 11:46:33
User entered '28 Feb 2021 11:46:29'	System	28 Feb 2021 11:46:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-08T08:31:00-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'da4a04e3-22bd-4605-9911-fef25734adee'	System	08 Mar 2021 13:31:11
User entered 'No (N)'	System	08 Mar 2021 13:31:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-08T08:31:02-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'da4a04e3-22bd-4605-9911-fef25734adee'	System	08 Mar 2021 13:31:11
User entered 'No (N)'	System	08 Mar 2021 13:31:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-08T08:31:06-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'da4a04e3-22bd-4605-9911-fef25734adee' User entered '08 Mar 2021 08:31:06'	System	08 Mar 2021 13:31:11
	System	08 Mar 2021 13:31:11

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-14T13:48:25-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3721448a-bab1-48ef-894a-7900f3245601'	System	14 Mar 2021 17:48:33
User entered 'No (N)'	System	14 Mar 2021 17:48:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-14T13:48:27-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3721448a-bab1-48ef-894a-7900f3245601'	System	14 Mar 2021 17:48:33
User entered 'No (N)'	System	14 Mar 2021 17:48:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-14T13:48:30-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '3721448a-bab1-48ef-894a-7900f3245601'	System	14 Mar 2021 17:48:33
User entered '14 Mar 2021 13:48:30'	System	14 Mar 2021 17:48:33

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-21T22:10:12-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bcb433fa-1404-47a0-be2e-59179f2f24ab'	System	22 Mar 2021 02:10:21
User entered 'No (N)'	System	22 Mar 2021 02:10:21

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-21T22:10:14-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bcb433fa-1404-47a0-be2e-59179f2f24ab'	System	22 Mar 2021 02:10:21
User entered 'No (N)'	System	22 Mar 2021 02:10:21

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-21T22:10:17-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'bcb433fa-1404-47a0-be2e-59179f2f24ab'	System	22 Mar 2021 02:10:21
User entered '21 Mar 2021 22:10:17'	System	22 Mar 2021 02:10:21

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-30T12:14:22-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '79073d58-89f3-4bc1-8b07-2be54f72d225'	System	30 Mar 2021 16:18:17
User entered 'No (N)'	System	30 Mar 2021 16:18:17

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-30T12:14:24-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '79073d58-89f3-4bc1-8b07-2be54f72d225'	System	30 Mar 2021 16:18:17
User entered 'No (N)'	System	30 Mar 2021 16:18:17

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-03-30T12:14:26-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '79073d58-89f3-4bc1-8b07-2be54f72d225'	System	30 Mar 2021 16:18:17
User entered '30 Mar 2021 12:14:26'	System	30 Mar 2021 16:18:17

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-04T17:30:19-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '530de9be-19e5-4da6-834a-875b4ec48a7b' User entered 'No (N)'	System	04 Apr 2021 21:30:27
	System	04 Apr 2021 21:30:27

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-04T17:30:21-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '530de9be-19e5-4da6-834a-875b4ec48a7b'	System	04 Apr 2021 21:30:27
User entered 'No (N)'	System	04 Apr 2021 21:30:27

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-04T17:30:23-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '530de9be-19e5-4da6-834a-875b4ec48a7b' User entered '04 Apr 2021 17:30:23'	System	04 Apr 2021 21:30:27
	System	04 Apr 2021 21:30:27

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-12T08:40:03-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6a6bb18c-b3ec-4d5a-bb00-2bf8196056b0' User entered 'No (N)'	System	15 Apr 2021 13:31:48
	System	15 Apr 2021 13:31:48

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-12T08:40:05-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6a6bb18c-b3ec-4d5a-bb00-2bf8196056b0' User entered 'No (N)'	System	15 Apr 2021 13:31:48
	System	15 Apr 2021 13:31:48

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-12T08:40:08-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '6a6bb18c-b3ec-4d5a-bb00-2bf8196056b0' User entered '12 Apr 2021 08:40:08'	System	15 Apr 2021 13:31:48
	System	15 Apr 2021 13:31:48

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-19T08:21:03-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'eb03704f-f4ee-4862-a8ea-819f04b25baf'	System	19 Apr 2021 12:21:13
User entered 'No (N)'	System	19 Apr 2021 12:21:13

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-19T08:21:05-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'eb03704f-f4ee-4862-a8ea-819f04b25baf'	System	19 Apr 2021 12:21:13
User entered 'No (N)'	System	19 Apr 2021 12:21:13

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-19T08:21:08-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'eb03704f-f4ee-4862-a8ea-819f04b25baf'	System	19 Apr 2021 12:21:13
User entered '19 Apr 2021 08:21:08'	System	19 Apr 2021 12:21:13

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-25T17:58:03-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2584b05b-8251-4b3b-acce-987e09899b97'	System	29 Apr 2021 16:16:34
User entered 'No (N)'	System	29 Apr 2021 16:16:34

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-25T17:58:04-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2584b05b-8251-4b3b-acce-987e09899b97'	System	29 Apr 2021 16:16:34
User entered 'No (N)'	System	29 Apr 2021 16:16:34

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-04-25T17:58:07-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: '2584b05b-8251-4b3b-acce-987e09899b97'	System	29 Apr 2021 16:16:34
User entered '25 Apr 2021 17:58:07'	System	29 Apr 2021 16:16:34

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-05-02T11:19:02-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b9c9c985-74aa-4f06-a950-d38b7c742f0b'	System	02 May 2021 15:19:14
User entered 'No (N)'	System	02 May 2021 15:19:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-05-02T11:19:05-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b9c9c985-74aa-4f06-a950-d38b7c742f0b'	System	02 May 2021 15:19:14
User entered 'No (N)'	System	02 May 2021 15:19:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-05-02T11:19:08-04:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'b9c9c985-74aa-4f06-a950-d38b7c742f0b'	System	02 May 2021 15:19:14
User entered '02 May 2021 11:19:08'	System	02 May 2021 15:19:14

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:32:12

US3602030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:32:12
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:32:12

US3602030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-28T06:46:40-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'efc044ac-c863-4d32-acbf-307e5cad02a'	System	28 Feb 2021 11:46:44
User entered 'No (N)'	System	28 Feb 2021 11:46:44

US3602030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A23FC290-850C-465F-AA5D-DACFEF00D83D)', Time: '2021-02-28T06:46:43-05:00', User OID: 'PatientReportedOutcome (US3602030)', ODM File OID: 'efc044ac-c863-4d32-acbf-307e5cad02a' User entered '28 Feb 2021 11:46:43'	System	28 Feb 2021 11:46:44
	System	28 Feb 2021 11:46:44

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:00:41

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:00:41

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:00:41

US3602030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:00:41

US3602030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:00:49

US3602030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:22:34
User entered '1'	System	15 Dec 2020 16:00:49

US3602030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:53:11

US3602030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:53:11

US3602030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:53:11

US3602030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:53:11

US3602030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:53:22

US3602030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User entered '1'	System	27 Jan 2021 14:53:22

US3602030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:27:30

US3602030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:27:30

US3602030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:27:30

US3602030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:43:55
User entered 'OL- Visit 2 D 29 and Part -A D 149 Safety Call (2/13/2021 +/- 3) overlapped and were combined. All assessments and procedures were completed as per protocol on 11/Feb/2021..' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:43:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:27:30

US3602030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:27:36

US3602030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User entered '1'	System	17 Feb 2021 21:27:36

US3602030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:08:13

US3602030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	15 Mar 2021 18:18:29
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Mar 2021 18:18:29
User entered '15 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:18:29
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 18:08:13
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 18:08:13

US3602030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:08:13

US3602030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:08:13

US3602030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:19:30

US3602030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:31:02
User entered 'I'	System	15 Mar 2021 18:19:30

US3602030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:02:54

US3602030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:02:54

US3602030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:02:54

US3602030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 15:02:54

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '08:30'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User entered '16 Apr 2021 08:30'	System	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 03:22:16
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 'NCS' (Site from System).	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
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).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:36
User entered '96.0' F	System	16 Apr 2021 15:04:26
	(b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '76'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
Comment added 'NCS'.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:47
User entered '156'	(b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
Comment added 'NCS'.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:04:58
User entered '92'	(b) (4), (b) (6)	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 15:04:26

US3602030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:15

US3602030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:15

US3602030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:27

US3602030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:27

US3602030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '08:40'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:27

US3602030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User entered '16 Apr 2021 08:40'	System	16 Apr 2021 15:05:27

US3602030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:05:33

US3602030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:05:33

US3602030

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:02

US3602030

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:02

US3602030

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:02

US3602030

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 17:12:02

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:17:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:51:24

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:17:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:51:24

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:22:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:22:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '1'	System	19 Jan 2021 17:12:19

US3602030

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '1'	System	19 Jan 2021 17:12:19

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	19 Jan 2021 17:13:47
DataPoint set to visible.	System	19 Jan 2021 17:12:19

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	19 Jan 2021 17:13:47
DataPoint set to visible.	System	19 Jan 2021 17:12:19

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '09:10'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '15 Jan 2021 09:10'	System	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '65'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'bpm'	System	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'breaths/min'	System	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '136'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:13:47

US3602030

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	19 Jan 2021 17:13:47
DataPoint set to visible.	System	19 Jan 2021 17:12:19

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11:25'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '15 Jan 2021 11:25'	System	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '68'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'bpm'	System	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'breaths/min'	System	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '125'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '83'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:25

US3602030

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mmHg'	System	19 Jan 2021 17:14:25

US3602030

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:39

US3602030

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:14:39

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:05

US3602030

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered empty.	System	19 Jan 2021 17:15:05

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'mRNA-1273'	System	19 Jan 2021 17:15:19
DataPoint set to visible.	System	19 Jan 2021 17:12:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '10:40'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '15 Jan 2021 10:40'	System	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'ONCE'	System	19 Jan 2021 17:15:19

US3602030

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 17:15:19

US3602030

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:35

US3602030

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:35

US3602030

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '09:45'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:35

US3602030

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '15 Jan 2021 09:45'	System	19 Jan 2021 17:12:35

US3602030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:48

US3602030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 15-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 14-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:49:34
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 15-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 14-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' answered with 'Subject was seen 1/15/21' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 16:21:32
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 15-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 14-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 03:47:35
User entered '15 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 17:12:48

US3602030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '08:40'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:48

US3602030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '15 Jan 2021 08:40'	System	19 Jan 2021 17:12:48

US3602030

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

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:12:54

US3602030

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

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:18:54
User entered '1'	System	19 Jan 2021 17:12:54

US3602030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:42

US3602030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:42

US3602030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:42

US3602030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:42

US3602030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:47

US3602030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '1'	System	11 Feb 2021 16:55:47

US3602030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '1'	System	11 Feb 2021 16:55:47
DataPoint set to visible.	System	11 Feb 2021 16:55:47

US3602030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:59

US3602030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:59

US3602030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:55:59

US3602030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'OLD29'	System	11 Feb 2021 16:55:59

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '08:21'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '11 Feb 2021 08:21'	System	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '85'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'bpm'	System	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'breaths/min'	System	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '140'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '92'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	11 Feb 2021 16:57:05

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '10:31'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '11 Feb 2021 10:31'	System	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '84'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'bpm'	System	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'breaths/min'	System	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '122'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	12 Feb 2021 17:55:34

US3602030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:15

US3602030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:15

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 03:34:57
Query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:36:15
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Feb 2021 14:36:08
User opened query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 05:09:40
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered empty.	System	11 Feb 2021 16:57:24

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User entered 'mRNA-1273'	System	11 Feb 2021 16:57:45
DataPoint set to visible.	System	11 Feb 2021 16:55:47

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '10:01'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User entered '11 Feb 2021 10:01'	System	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User entered 'ONCE'	System	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 16:57:45

US3602030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:57:56

US3602030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:22
User entered '1'	System	11 Feb 2021 16:57:56

US3602030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:49:49

US3602030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:49:49

US3602030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:49:49

US3602030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:49:49

US3602030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:49:55

US3602030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '1'	System	24 Feb 2021 17:49:55

US3602030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:28

US3602030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:28

US3602030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:28

US3602030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'OLD57'	System	11 Mar 2021 15:07:28

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '08:20'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '11 Mar 2021 08:20'	System	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'bpm'	System	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'breaths/min'	System	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
Comment added 'BP first measured at 08:20h 183/77 (NCS), currently entered data was repeated BP collected at 08:30h.'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:04
User entered '146'	(b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '87'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered 'mmHg'	System	11 Mar 2021 15:08:51

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30

US3602030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30

US3602030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:20

US3602030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:20

US3602030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:36

US3602030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:36

US3602030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '08:55'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:11:36

US3602030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:30
User entered '11 Mar 2021 08:55'	System	11 Mar 2021 15:11:36

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:09:20**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:47
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:09:20**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:47
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:09:20**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:47
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:09:20**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:47
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:09:20**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:47
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:10:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: Unscheduled 22 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '08:52'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User entered '22 Sep 2020 08:52'	System	05 Mar 2021 18:21:05

US3602030

Folder: Unscheduled 22 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
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)	08 Mar 2021 04:37:16
Comment added 'NCS as per provider.'	(b) (4), (b) (6)	05 Mar 2021 18:22:03
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 'NCS' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 18:21:44
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	05 Mar 2021 18:21:05
User entered '96.4' F	(b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: Unscheduled 22 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '98'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User entered 'bpm'	System	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '12'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User entered 'breaths/min'	System	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '128'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User entered 'mmHg'	System	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53
User entered 'mmHg'	System	05 Mar 2021 18:21:05

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Vital Signs**

Generated On: **10 Jun 2021 09:09:20**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:53

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Physical Examination**

Generated On: **10 Jun 2021 09:09:20**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:57
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:22:34

US3602030

Folder: **Unscheduled 22 Sep 2020**

Form: **Physical Examination**

Generated On: **10 Jun 2021 09:09:20**

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:52:57
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:22:34

US3602030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:09:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:07
User closed query 'Per DM CLR: Per Day 138 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:50:02
Query 'Per DM CLR: Per Day 138 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject did not report an AE or MAAE during their OL-D8 Safety Call on 22-Jan-2021. Subject did report an MAAE since their last contact with the site on OL-V2D29 on 11-Feb-2021, which has been recorded in AE Log, however, this MAAE start date 04-Feb-2021.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 20:05:39
User opened query 'Per DM CLR: Per Day 138 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:13:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:20:04

US3602030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:09:20

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:48:41

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:38:48
User entered 'USA-US079-2020-mRNA-1273-P301000001'	System	23 Sep 2020 11:38:43
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 11:38:43

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling face, LLT: Swelling of face - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:25:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:25:32
Data point term sent to Coder	System	09 Oct 2020 19:21:42
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' (Site from System).	System	09 Oct 2020 19:21:37
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' answered with 'will update' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 19:21:37
Data point term sent to Coder	System	09 Oct 2020 19:10:17
User entered 'SWELLING TO THE RIGHT SIDE OF THE FACE' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:09:23
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. SWELLING FACE / TINGLING with location / NUMBENESS with location' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 11:02:18
Data point term sent to Coder	System	22 Sep 2020 14:13:08
User entered 'Swelling to the right side of the face and tingling numbness'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '17 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:46:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:22
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:12:38
User entered '16:00'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:46:22
User entered '17 Sep 2020 16:00'	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '27 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
Query 'PV query: Please provide the stop date for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:49:59
User opened query 'PV query: Please provide the stop date for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Sep 2020 14:46:35
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Sep 2020 14:46:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Sep 2020 14:12:38
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:35
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Related (RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
Query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:03
User opened query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:36:29
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0' reason for change: New Information	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:56:38
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:37:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:46:02
Query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:23:22
User closed query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:53:54
User opened query 'Per CDM: Please consider updating the Concomitant Procedure page with this AE or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:53:51
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:56:38
Query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:37:50
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 15:37:34
User opened query 'Per DM CLR: RQ: Response noted, however, there were no updates provided. Please make sure a therapeutic procedure is recorded for this AE or update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:10:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:49:40

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:24:13
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:28:01
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:24:15
Query 'PV query: Please provide the final outcome for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:06
User opened query 'PV query: Please provide the final outcome for the event of swelling to the right side of the face and tingling numbness, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:34:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:08:51
User closed query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:26:13
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:34:49
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:48:22
User closed query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:53:13
Query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:21:34
User opened query 'Per DM CLR: SAE Narrative = HAD HER TOOTH CLEANING AND ROOT CANAL DONE AUG 6TH AND AUGUST 28TH and PMHX OF SINUS SURGERIES IN THE PAST. However, these information were not recorded in the Med History eCRF. Please review and ensure that these are captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:28:10
Query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:14

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:50:11
User opened query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:59
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:36
User entered 'pt had Her IP on sep 11th Had her tooth cleaning and root canal done Aug 6th and august 28th and was well prior to the vaccine PMHx of sinus surgeries in the past No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th Over the next 24hr had increasing tingling and numbness along the jaw line and increasing swelling and fullness over the maxilla No nasal discharge The pain persisted on the weekend and she saw her dentist on 9/21 and called me from there since The dentist did not find any issues with the tooth and felt that it could be shingles and of some other medical issues leading to referred pain On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness rec : seek eval by ENT and or medical doctor Have the dentist and the other physicians she sees to fax the records to us (b) (6) '	(b) (4), (b) (6)	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 14:12:38

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:13
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	23 Sep 2020 11:39:08

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Vaccination related complications, PT: Immunisation anxiety related reaction, LLT: Immunization anxiety related reaction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:20:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:20:21
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:06:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:06:41
Data point term sent to Coder	System	22 Sep 2020 14:38:47
User entered 'Anxiety Related to the Vaccine'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:46:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 14:44:14
User entered '16:00' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:46:01
User entered '17 Sep 2020 16:00'	System	22 Sep 2020 14:44:14
User entered empty.	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:26:10
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:26:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:25:27
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:28
Query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:38
User entered '7 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 19:25:27
User opened query 'PV query: Please provide the stop date for the event of anxiety related to the vaccine., when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Related (RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:33
Query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' answered with 'drug was not withdrawn' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:13
User opened query 'PV query: Please confirm if the study drug was withdrawn in response to the events. If so, please update the action taken.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:38
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this AE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM). Query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this AE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was given.' answered with 'subject was not treated for the anxiety related to the vaccine.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:57:12
Query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this AE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was given.' answered with 'subject was not treated for the anxiety related to the vaccine.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:51:10
User opened query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this AE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 12:41:12
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 15:38:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:54:59
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:38:27
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 15:38:17
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query ' Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:38:43
Query ' Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' answered with 'patient was seen for an illness visit.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:39:22
User opened query ' Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this eve. Please uncheck the box or else review and clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:05:51

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:57:03
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4), (b) (6)	15 Oct 2020 13:24:24
' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4), (b) (6)	15 Oct 2020 09:25:45
' (Site from DM). User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 12:53:37
Query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 19:25:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:25:27
User opened query 'PV query: Please provide the final outcome for the event of anxiety related to the vaccine, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: SAE Narrative = PAIN ON CHEWING IN THE BACK TEETH. Review if this should be recorded as a separate Adverse Event. If so. Please update AE ecrf. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 03:49:06
Query 'Per DM CLR: SAE Narrative = PAIN ON CHEWING IN THE BACK TEETH. Review if this should be recorded as a separate Adverse Event. If so. Please update AE ecrf. Else, clarify.' answered with 'documented and updated' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 18:57:01
User opened query 'Per DM CLR: SAE Narrative = PAIN ON CHEWING IN THE BACK TEETH. Review if this should be recorded as a separate Adverse Event. If so. Please update AE ecrf. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:24:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 14:44:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 14:44:14
User entered 'No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:44:14

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 14:38:21
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:38:21

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:28:03
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:27:49

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Facial paraesthesia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:08:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:08:33
Data point term sent to Coder	System	09 Oct 2020 19:13:22
User entered 'Tingling on Right Side of Face'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '17 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:13:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:13:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:12:42
User entered '4:00'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:13:16
User entered '17 Sep 2020 4:00'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:19:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Oct 2020 19:19:18
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:19:18
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 19:17:29
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	09 Oct 2020 19:17:29
User entered '7 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:17:29
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	09 Oct 2020 19:12:42
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:13:16
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:12:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:13:16
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:19:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:08
User closed query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:44:08
User closed query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:41:06
Query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' answered with 'will update' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:41:05
Query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' answered with 'ENT feels the tingling is odontogenic' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:41:00
User opened query 'PV query: Please consider adding sinus surgery to the medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:30:38
User opened query 'PV query: Please confirm if the subject went to ENT and what their diagnosis was.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'pt had Her IP on sep 11th Had her tooth cleaning and root canal done Aug 6th and august 28th and was well prior to the vaccine PMHx of sinus surgeries in the past No issues related tot he vaccine itself but then on Thursday started with pain on chewing in the back teeth and thought was related to the root canal and never mentioned it on the safety call with me on Friday the 18th Over the next 24hr had increasing tingling and numbness along the jaw line and increasing swelling and fullness over the maxilla No nasal discharge The pain persisted on the weekend and she saw her dentist on 9/21 and called me from there since The dentist did not find any issues with the tooth and felt that it could be shingles and of some other medical issues leading to referred pain On today's limited exam: Vitals : 96.4 , 128/81, plse ox 100% HR 98 rr 12 BMI 38.4 she does have swelling to the cheek and jaw area No redness to the face No tooth decay noted , no pain on palpation of the tooth No swelling of the jaw No facial droop No nasal congestion or redness rec : seek eval by ENT and or medical doctor Have the dentist and the other physicians she sees to fax the records to us (b) (6) '	(b) (4), (b) (6)	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:12:42

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:28:43
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:28:38

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:16
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Pleuritic pain, LLT: Pleuritic pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
Data point term sent to Coder	System	09 Oct 2020 19:28:58
User entered 'Left sided Pleuritic chest pain'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '27 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '29 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:30:56
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:28:14
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:28:06
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:57:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:30:59
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:28:19
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:28:06
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:58:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:57:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Narrative indicates that subject had "CXR". However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:34:48
Query 'Per DM CLR: Narrative indicates that subject had "CXR". However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:51:45
User opened query 'Per DM CLR: Narrative indicates that subject had "CXR". However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:39:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:57:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:40
User closed query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:34
User closed query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:45:10

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no additional medications or treatment. subject should continue q6o FU with Cardiologist' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:48:31
Query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' answered with 'regular stress test no ischemia, ehco shows: Left ventricle cavity is normal in size. Normal global wall motion. Visual EF is 55-60%. Doppler evidence of grade I (impaired) diastolic dysfunction. Structurally normal trileaflet aortic valve with mild (Grade I) Regurgitation.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:47:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' answered with 'states "all tests were negative" do not have physical lab result' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:44:28
User opened query 'PV Query: Please provide treatment given for the event of pleuritic chest pain, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:27:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results for the event of pleuritic chest pain. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:27:07

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: It was reported that stress test and echo were planned for Oct 13. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:26:48
User entered 'L sided back / thoracic chest pain so she went to her PCP on 9/28 and had an ekG done which was normal . SHe had labs done today (nl) and Had a CXR done which was also normal . . No meds and no OTC take thus far . Was sent to the cardiologist (b) (6) , whom she saw today 10/7 and had evaluation Done . He did not think it is cardiac in origin but rec echo (10/9) and stress test on (10/13)'	(b) (4), (b) (6)	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:29:22
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:29:17

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'no subject followed up with cardiologist' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:54:19
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:46:41
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Feeling hot, LLT: Localised feeling of warmth - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:49
Data point term sent to Coder	System	09 Oct 2020 19:31:00
User entered 'Left sided chest wall warmth'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:30:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 19:30:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:30:38
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:48:20
Query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:54:02
User entered '16 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'PV query: Please provide the stop date of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:23:18
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:32:47
Query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' answered with 'updated to correct action' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:54:10
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:04:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:34:37
Query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' answered with 'The procedures were done in response to the subjects symptoms' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:52:24
User opened query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:42:58
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:16:46
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:38:53
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:39:28

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query ' Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you. ' answered with 'subject was seen by other medical professionals' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:54:28
User opened query ' Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please confirm and update or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:09:26
Query ' Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:07:10
User opened query ' Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:06:09
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User closed query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:49:09
Query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:54:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:55
User opened query 'PV query: Please provide the final outcome of left sided chest wall warmth, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:23:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:46
User entered 'Will Not be pursuing the second Dose of the investigational product Started with chest wall pain and tingling and feeling of warmth to the side that started yesterday evening while lying down And mentioned it to the cardiologist too . SHE has been recommended to have the neurologist assess her for any etiology for the symptoms Pt is going to be making an appt and will let us know the outcome	(b) (4), (b) (6)	09 Oct 2020 19:30:23

She does ask me to un blind her from the study given various symptoms with no diagnosis made and concern for vaccine related issues

I have had the discussion with (b) (6) reg the same'

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:30:23

US3602030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:30:38

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:29:56
User entered 'USA-US079-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 12:29:51

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:56:05
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Localized tingling - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:10:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:10:33
Data point term sent to Coder	System	09 Oct 2020 19:43:21
User entered 'Left Sided Tingling'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 04:53:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:53:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 04:52:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:46:56
Query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:53:04
User entered '16 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'PV query: Please provide the stop date of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:25:09
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:34:38
Query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' answered with 'updated to correct action' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:52:50
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however Dosing Discontinuation page is not completed. Please consider to complete all applicable forms. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:07:40
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:34:23
Query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' answered with 'The procedures were done in response to the subjects symptoms and this AE' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:52:52
User opened query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are only diagnostic. Please review the response or record any therapeutic procedure done for this AE. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:43:30
User closed query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:17:05
Query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:39:01
User opened query 'Per DM CLR: RQ: Response noted, however, please confirm any therapeutic procedure/s was done during the visit and add those in the Con Proc eCRF. Otherwise, update the response as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:12:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:40:02

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' answered with 'Patient was seen by other medical professionals.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:51:50
User opened query 'Per CDM: Concomitant Procedure checkbox is selected However, no any procedure recorded related to this event. Please review and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:11:00
Query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:10:34
User opened query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:08:34
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:47:07
Query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:52:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	28 Oct 2020 04:52:14
User opened query 'PV query: PV query: Please provide the final outcome of left sided tingling, when available. Please do not response to the query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:24:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:52
User closed query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:46:42
Query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' answered with 'Subject has not seen neurology as of yet' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 04:52:31
User opened query 'PV Query: Please provide the of the neurology consult for pain, warmth and tingling of the left side of the chest wall.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:24:44
User entered 'Started with chest wall pain and tingling and feeling of warmth to the side that started yesterday evening while lying down And mentioned it to the cardiologist too . SHE has been recommended to have the neurologist assess her for any etiology for the symptoms Pt is going to be making an appt and will let us know the outcome	(b) (4), (b) (6)	09 Oct 2020 19:42:33

She does ask me to un blind her from the study given various symptoms with no diagnosis made and concern for vaccine related issues

I have had the discussion with (b) (6) reg the same'

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:42:33

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:28:13
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'No, this was a SAR and in the investigator's clinical judgment, this AE was related to the IP which was administered two days prior to the AE start date.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:22:14
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:49:55
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:55:15
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 15:42:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 15:42:51
Data point term sent to Coder	System	11 Mar 2021 15:42:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
Data point term sent to Coder	System	10 Feb 2021 21:28:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'Will remove AE, does not meet reporting criteria' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 21:27:58
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:09:52
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:56:30
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:57
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Oct 2020 06:28:11
Data point term sent to Coder	System	28 Oct 2020 04:56:55
User entered 'Headache'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria (i.e., eDiary HEADACHE Day 8 = NO Information). Please review and confirm if HEADACHE is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:41:14
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria (i.e., eDiary HEADACHE Day 8 = NO Information). Please review and confirm if HEADACHE is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:41:03
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 19OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:55:13
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 19OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'As per D8 Safety Call notes on 23-Oct-2020, subject reported AE start date a 18-Oct-2020.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:42:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 19OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:09:46
User entered '18 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '24 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'Related (RELATED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:19:42
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:51:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 15:51:34
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:25:35
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 11:35:10
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:54:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:54:16
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:45:02
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:54:16
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06
User entered '0'	System	28 Oct 2020 04:56:06

US3602030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 15:41:11
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Feb 2021 21:28:06

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as SOC: Nervous system disorders, HLGHT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 20:25:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 20:25:35
Data point term sent to Coder	System	11 Nov 2020 20:09:30
User entered 'Migraine Headache'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User entered empty.	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User entered empty.	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:35:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:54:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:44:35
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User entered '0'	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52
User entered '0'	System	11 Nov 2020 20:08:47

US3602030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:52

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as SOC: Nervous system disorders, HLGHT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 20:11:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 20:11:37
Data point term sent to Coder	System	11 Nov 2020 20:10:37
User entered 'Migraine Headache'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User entered empty.	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User entered empty.	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:52:17
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:35:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:55:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:44:42
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User entered '0'	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09
User entered '0'	System	11 Nov 2020 20:09:37

US3602030

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:09

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Sinus pain, LLT: Sinus pain - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 15:21:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 15:21:41
Data point term sent to Coder	System	08 Apr 2021 13:05:27
User closed query 'CDM Coding, please split the term 'RIGHT MAXILLARY SINUS PAIN/CONGESTION' into separate records, as 'RIGHT MAXILLARY SINUS PAIN' and 'CONGESTION'(Clarify Lung congestion/ Sinus congestion etc) reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	08 Apr 2021 13:05:26
Query 'CDM Coding, please split the term 'RIGHT MAXILLARY SINUS PAIN/CONGESTION' into separate records, as 'RIGHT MAXILLARY SINUS PAIN' and 'CONGESTION'(Clarify Lung congestion/ Sinus congestion etc) reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with "Term has been split as per query.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 13:05:26
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:04:47
User entered 'RIGHT MAXILLARY SINUS PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:04:47
User opened query 'CDM Coding, please split the term 'RIGHT MAXILLARY SINUS PAIN/CONGESTION' into separate records, as 'RIGHT MAXILLARY SINUS PAIN' and 'CONGESTION'(Clarify Lung congestion/ Sinus congestion etc) reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4)	08 Apr 2021 06:47:35

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:38:25
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was not assessed for potential COVID-19 infection. Subject made visited with their healthcare provider who assessed them and prescribed medication for this MAAE. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:16:46
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:17:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Data point term sent to Coder	(b) (4) System	11 Feb 2021 16:53:59
User entered 'Right Maxillary Sinus Pain/Congestion'	(b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:08:13
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	11 Feb 2021 16:54:21
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	11 Feb 2021 16:54:21
User entered '04 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:54:21
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	11 Feb 2021 16:53:54
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	11 Feb 2021 16:53:54
User entered '04 Feb 2020'	(b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User entered empty.	System	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:27:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:27:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:27:23
User entered '17 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:27:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User entered empty.	System	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:27:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:27:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:27:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:27:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User entered '0'	System	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17
User entered '1'	System	11 Feb 2021 16:53:54

US3602030

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:17

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User coded data point as SOC: Gastrointestinal disorders, HLG: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:39:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:39:01
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:08:13
Data point term sent to Coder	System	18 Feb 2021 18:58:12
User entered 'Right Tooth Ache'	(b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User entered empty.	System	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User entered empty.	System	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User entered '0'	System	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27
User entered '1'	System	18 Feb 2021 18:57:41

US3602030

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:27

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 13:23:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 13:23:00
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Apr 2021 01:12:01
Data point term sent to Coder	System	16 Apr 2021 15:07:49
User entered 'Post-Nasal Drip causing Pharyngitis'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:07:47

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 13:13:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 13:13:41
Data point term sent to Coder	System	08 Apr 2021 13:03:25
User entered 'RIGHT MAXILLARY SINUS Congestion'	(b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User entered empty.	System	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User entered empty.	System	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User entered '0'	System	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36
User entered '1'	System	08 Apr 2021 13:03:10

US3602030

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:09:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:24:36

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:09:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:20:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:11:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	11 Sep 2020 16:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:16:40
Data point term sent to Coder	System	11 Sep 2020 16:15:50
User entered 'Nexplanon'	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Contraception and Endometriosis'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'n/a'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'n/a'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'q 3years'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 16:15:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 16:15:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 16:15:31
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 16:14:55
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Intradermal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:15:31
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '24 Jun 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:14:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:21:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:21:45
Data point term sent to Coder	System	21 Oct 2020 18:20:30
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 18:19:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:17:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:17:37
Data point term sent to Coder	System	11 Sep 2020 16:16:58
User entered 'Advair'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Asthma' reason for change: New Information	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:19:43
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '250/50'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:59:22
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:02:16
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:29:51
User entered 'Other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:29:47
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:07:12
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 03:21:25
Query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:59:28
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Jan 2021 14:59:22
User opened query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:03:44
User entered 'mcg' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:29:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:16:29

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 16:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:18:39
Data point term sent to Coder	System	11 Sep 2020 16:18:03
User entered 'Telmisartan'	(b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '20'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:17:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Nov 2020 04:39:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:39:51
Data point term sent to Coder	System	29 Oct 2020 21:31:44
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:30:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:10:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:10:46
Data point term sent to Coder	System	11 Sep 2020 16:20:15
User entered 'Restasis 0.5 mg/ml'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Dry Eye'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '2'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'gtts'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 04:02:32
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:30:48
User entered 'Other (OTHER)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:30:43
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:08:32
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Ophthalmic' reason for change: New Information	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:30:43
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:19:58

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: ASTELIN [AZELASTINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	21 Nov 2020 15:56:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 15:56:00
Data point term sent to Coder	System	29 Oct 2020 21:31:45
Data point term sent to Coder	System	28 Oct 2020 04:56:55
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 04:56:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: ASTELIN [AZELASTINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:06:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:06:50
Data point term sent to Coder	System	24 Sep 2020 13:05:20
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	24 Sep 2020 13:04:33

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:04:33
Data point term sent to Coder	System	24 Sep 2020 13:04:17
User entered 'ASTELIN 0.15%' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:04:12
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 11:48:43
Data point term sent to Coder	System	11 Sep 2020 16:21:16
User entered 'OTC Astelin 0.15%'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 04:02:38
Query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:31:30
User entered 'Non- Allergic RHINITIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:31:25
User opened query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:08:50
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 06:23:51
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:56:39
User entered 'Nasal (NASAL)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Oct 2020 04:56:31
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:28:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:21:09

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 21:33:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:33:46
Data point term sent to Coder Coding entries removed.	System	29 Oct 2020 21:32:51
	(b) (4), (b) (6)	29 Oct 2020 21:32:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:15:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:15:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:23:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:23:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

2569 of 2977

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Sep 2020 16:22:18
User entered 'Nexium'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 04:06:31
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'acid reflux is GERD by the way. updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:32:54
User entered 'Acid Reflux' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:32:03
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:18
User entered 'GERD'	(b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '20'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:22:08

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 16:10:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 16:10:25
Data point term sent to Coder	System	29 Oct 2020 21:33:53
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:33:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 09:47:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 09:47:37
Data point term sent to Coder	System	11 Sep 2020 16:23:23
User entered 'Flonase 50mcg'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 04:06:43
Query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:33:13
User entered 'Non- Allergic RHINITIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:33:09
User opened query 'Per DM CLR: Please update indication to clarify whether 'Rhinitis Infective' or 'Allergic Rhinitis'. Please review and update as appropriate and ensure indication is reconciled with any corresponding AE or MH, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:28
User entered 'Rhinitis'	(b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '2'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:23:03

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 21:47:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:47:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Oct 2020 21:33:53 29 Oct 2020 21:33:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 10:13:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 10:13:49
Data point term sent to Coder User entered 'Diclofenac'	System (b) (4), (b) (6)	11 Sep 2020 16:24:24 11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 04:06:49
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:33:44
User entered 'LEFT KNEE OA' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Oct 2020 21:33:39
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:09:46
User entered 'Left Knee Pain'	(b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '100'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 16:24:06

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 14:29:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 14:29:27
Data point term sent to Coder	System	16 Oct 2020 14:28:12
User entered 'Melatonin'	(b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '3'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '2x a week'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 14:27:59

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 14:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Oct 2020 14:30:31
Data point term sent to Coder	System	16 Oct 2020 14:29:14
User entered 'Multivitamin'	(b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Good Health'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:28:28

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 15:27:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:27:31
Data point term sent to Coder	System	16 Oct 2020 14:31:18
User entered 'Biotin'	(b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Thinning of Hair'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'UN Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:31:07

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 15:36:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:36:33
Data point term sent to Coder	System	16 Oct 2020 14:32:19
User entered 'Vitamin D'	(b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Maintain Good Level'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '2000'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Units'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:31:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 15:40:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:40:35
Data point term sent to Coder	System	16 Oct 2020 14:33:19
User entered 'Probiotic'	(b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Good GI Health'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:32:27

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
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.	(b) (4) Coder Import (b) (4)	28 Oct 2020 06:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Oct 2020 06:28:12
Data point term sent to Coder	System	28 Oct 2020 04:57:56
User entered 'Tylenol'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User closed query 'Per DM CLR re-query: Response noted. However, there is no corresponding data on Diary or AE that matches this Con Med indication during this timeframe. Please reconcile Conmed Indication/Dates and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:57:17
Query 'Per DM CLR re-query: Response noted. However, there is no corresponding data on Diary or AE that matches this Con Med indication during this timeframe. Please reconcile Conmed Indication/Dates and update as appropriate, else clarify.' answered with 'Corresponding AE "Headache" was previously recorded, but inactivated in AE Log. Corresponding AE "Headache" entry has been reactivated in AE Log.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:45:40
User opened query 'Per DM CLR re-query: Response noted. However, there is no corresponding data on Diary or AE that matches this Con Med indication during this timeframe. Please reconcile Conmed Indication/Dates and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:50:51
User closed query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:50:51
Query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' answered with 'AR did not meet AE reporting criteria and was, therefore, not recorded in AE Log.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 17:35:55

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	09 Mar 2021 04:09:35
User entered 'Headache'	Bindu Balani (b) (4) (b) (4) (b) (4), (b) (6) [REDACTED]	19 Feb 2021 22:08:13 28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '500'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '18 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '18 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:48:59
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 21:26:11
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'These are the dates reported by the subject, will update to no' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 21:26:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:09:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:26
User entered empty.	System	28 Oct 2020 04:57:20

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 21:26:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 21:26:03
Data point term sent to Coder	System	16 Feb 2021 14:03:54
Coding entries removed.	(b) (4), (b) (6)	16 Feb 2021 14:03:25
User entered 'EXCEDRIN MIGRAINE (acetaminophen/aspirin/caffiene)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:03:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Oct 2020 06:28:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Oct 2020 06:28:14
Data point term sent to Coder	System	28 Oct 2020 04:58:56
User entered 'Excedrin Migraine'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '250/250/65' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:03:25
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:03:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR Re-query: Response noted. However, "Headache" has been recorded with the start date of "23OCT2020" (8th Day) which is outside the SAR period. Please reconcile and update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 02:54:29
Query 'Per DM CLR Re-query: Response noted. However, "Headache" has been recorded with the start date of "23OCT2020" (8th Day) which is outside the SAR period. Please reconcile and update as appropriate, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:52:34
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Feb 2021 18:52:31
User opened query 'Per DM CLR Re-query: Response noted. However, "Headache" has been recorded with the start date of "23OCT2020" (8th Day) which is outside the SAR period. Please reconcile and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:16:23
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:16:23
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'These are the dates reported by the subject, since it falls between the first 7days post IP, it is still a solicited AE' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 21:26:45

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not recorded on eDiary on the given date and considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:09:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:29
User entered empty.	System	28 Oct 2020 04:58:04

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 21:26:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 21:26:02
Data point term sent to Coder Coding entries removed.	System	16 Feb 2021 14:01:53
	(b) (4), (b) (6)	16 Feb 2021 14:01:34
User entered 'EXCEDRIN (ACETAMINOPHEN /ASPIRIN/CAFFEINE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:01:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:46:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:46:55
Data point term sent to Coder Coding entries removed.	System	12 Feb 2021 17:53:58
	(b) (4), (b) (6)	12 Feb 2021 17:53:22
User entered 'EXCEDRIN (acetaminophen 250mg/aspirin 250mg, caffeine 65 mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Feb 2021 17:53:22

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:08:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:08:17
Data point term sent to Coder	System	30 Dec 2020 16:07:10
User entered 'Excedrin'	(b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR RQ: Response noted. As per CCG V.5.0 page 53, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please consider updating 'Dose per administration' field to "250/250/65".' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 02:34:47
Query 'Per DM CLR RQ: Response noted. As per CCG V.5.0 page 53, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please consider updating 'Dose per administration' field to "250/250/65".' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:01:04
User entered '500/500/130' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:00:51
User opened query 'Per DM CLR RQ: Response noted. As per CCG V.5.0 page 53, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please consider updating 'Dose per administration' field to "250/250/65".' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:12:55
User closed query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:12:55
Query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' answered with 'It is too long to enter to the field, However since the subject took 2 tablets it would seem easier to have them separate' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:52:01

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:21:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:21:10
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated name of medication with dosage' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:53:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 03:44:18
User entered '2'	(b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR RQ: Please consider updating 'dose unit' field to "mg".' (Site from DM).	(b) (4)	17 Feb 2021 02:33:16
Query 'Per DM CLR RQ: Please consider updating 'dose unit' field to "mg".' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:01:11
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:00:51
User opened query 'Per DM CLR RQ: Please consider updating 'dose unit' field to "mg".' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:15:02
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User entered empty.	System	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User entered empty.	System	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:36
User entered empty.	System	30 Dec 2020 16:06:48

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 14:03:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 14:03:57
Data point term sent to Coder Coding entries removed.	System	16 Feb 2021 14:02:53
	(b) (4), (b) (6)	16 Feb 2021 14:02:13
User entered 'EXCEDRIN(ACETAMINOPHEN/ASPIRIN/CAFFEINE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:02:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:48:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:48:55
Data point term sent to Coder Coding entries removed.	System	12 Feb 2021 17:53:58
	(b) (4), (b) (6)	12 Feb 2021 17:53:44
User entered 'EXCEDRIN(acetaminophen 250mg/aspirin 250mg, caffeine 65 mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Feb 2021 17:53:44

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:11:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:11:17
Data point term sent to Coder	System	30 Dec 2020 16:10:13
User entered 'Excedrin'	(b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 05:35:37
User entered '500/500/130' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 14:02:13
Query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' answered with 'It is too long to enter to the field, However since the subject took 2 tablets it would seem easier to have them separate' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:52:06
User opened query 'Per DM CLR RQ: Site update noted. However, please consider moving doses from 'name of medication' field to 'Dose per administration' field and update as "250/250/65" and 'dose unit' field to "mg" to reflect "ACETAMINOPHEN 250MG/ASPIRIN 250MG, CAFFEINE 65 MG".' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:22:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate. (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:22:25
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate. answered with 'updated name of medication with dosage' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:53:57

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this combination drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). User entered '2'	(b) (4), (b) (6)	11 Feb 2021 03:44:38
	(b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:02:13
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User entered empty.	System	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User entered empty.	System	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:41
User entered empty.	System	30 Dec 2020 16:09:43

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 12:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 12:20:56
Data point term sent to Coder	System	11 Feb 2021 16:52:58
User entered 'Keflex'	(b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Right Maxillary Sinus Pain/Congestion'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '500'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:29:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:29:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:29:20
User entered '16 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:29:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User entered '2'	System	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User entered '1'	System	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:22:52
User entered '804 (804)'	System	11 Feb 2021 16:52:41

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:16:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:16:33
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Apr 2021 01:12:01
Data point term sent to Coder	System	16 Apr 2021 15:09:51
User entered 'Keflex'	(b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Post-nasal drip causing pharyngitis'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '500'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Apr 2021 15:09:55
User entered '7 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 15:09:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	16 Apr 2021 15:09:42
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:09:42

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:09:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	15 Oct 2020 13:23:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:19:30
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 13:19:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 14:46:54
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:11:53

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:59:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:19:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:20
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' answered with 'for the AE reported, it was asked that I put the visit here.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:48:49
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review and record the actual medical procedure done, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 05:36:16
User entered 'Dentist Visit'	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:12
User entered 'Medical History (MH)'	(b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:20

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:23:59

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'EKG'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:35

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Stress Test'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:39:57

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:51:24

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Chest X-Ray (CXR)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:51:24

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:51:24

US3602030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:51:24

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '23/Sep/2020 07:39'	(b) (4) System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:20

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '08/Oct/2020 12:50'	(b) (4) System	08 Oct 2020 12:50:39

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:31:06
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 12:50:39

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:09:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '12/Oct/2020 12:31'	(b) (4) System	12 Oct 2020 12:31:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:50:20
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 12:31:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:09:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '28/Oct/2020 15:33'	(b) (4) System	28 Oct 2020 19:33:58

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:50:20
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 19:33:58

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:09:20

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '29/Oct/2020 09:51'	(b) (4) System	29 Oct 2020 13:51:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:14
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 13:51:21

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:09:20

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '30/Oct/2020 08:37'	(b) (4) System	30 Oct 2020 12:37:25

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:36:09
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 12:37:25

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:09:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '10/Nov/2020 15:36'	(b) (4) System	10 Nov 2020 20:36:29

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:46:51
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 20:36:29

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'USA-US079-2020-MRNA-1273-P301000001'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:11
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:31:06
Un-reviewed for Safety.	System	12 Oct 2020 12:29:17
User entered 'Yes (Y)'	System	12 Oct 2020 12:29:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:23
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'No (N)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:27
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Yes (Y)'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:27:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Bindu'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'Balani'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:39:30
User entered 'NJ'	System	23 Sep 2020 11:38:43

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:28:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:50:24
User entered 'US'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
	(b) (4)	
User entered '8'	System	19 Nov 2020 19:47:07
User entered '7'	System	10 Nov 2020 20:36:29
User entered '6'	System	30 Oct 2020 12:37:25
User entered '5'	System	29 Oct 2020 13:51:21
User entered '4'	System	28 Oct 2020 19:33:58
User entered '3'	System	12 Oct 2020 12:31:21
User entered '2'	System	08 Oct 2020 12:50:39
User entered '1'	System	23 Sep 2020 11:39:37

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:09:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '19/Nov/2020 19:47'	(b) (4) System	19 Nov 2020 19:47:07

US3602030

Folder: SAE USA-US079-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:09:20

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.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:08:13
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:47:07