

US3602051 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:10:45

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US3602051

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

[Participant ID](#)

US3602051

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

US3602051

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3602051

Folder: Screening

Form: Demographics

Data signed: (b) (4) 27 Apr 2021 03:56:25

Generated On: 10 Jun 2021 09:10:45

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
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	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

US3602051

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Date of Informed Consent (dd MMM yyyy)	17 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

US3602051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3602051

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Were any significant conditions reported?

Yes ☒

No ☐

US3602051

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	HEADACHES (TYPE: TENSION)
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	BRONCHITIS (MILD)
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3602051

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	SMOKING
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

US3602051

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	ARTHRITIS (TYPE: UNKNOWN; LOCATION: KNEES BILATERALLY, NECK)
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3602051

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	SYNCOPE (RECURRENT)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	GENITAL HERPES (LAST OUTBREAK JULY 2020)
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602051

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	NON-SPECIFIC CARDIAC MURMUR (DIAGNOSED A FEW YEARS AGO)
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3602051

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	ROTATOR CUFF TEAR (RIGHT)
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3602051

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Condition	ROTATOR CUFF REPAIR (RIGHT)
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3602051

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:51 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:51
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	152 lb
BMI (<i>xxx.x</i>)	22.49341 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602051

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3602051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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

OUT OF WORK ON DISABILITY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3602051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 146508

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 ☒

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:51
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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.

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 14:25 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 14:25

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

US3602051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	11:51 (24 HR)
Collection date and time (derived)	17 SEP 2020 11:51

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:51	17 SEP 2020 11:51
Nasopharyngeal Swab 2	No		

US3602051

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 15:02

PC Open Date & Time

17 SEP 2020 14:45

PC Close Date & Time

17 SEP 2020 17:15

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 97.0 °F

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

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

PC Time Stamp	17 SEP 2020 22:37
PC Open Date & Time	17 SEP 2020 18:10
PC Close Date & Time	18 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:22

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

19 SEP 2020 21:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:28

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 21:07

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

22 SEP 2020 22:07

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:27

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 15:03

PC Open Date & Time

17 SEP 2020 14:45

PC Close Date & Time

17 SEP 2020 17:15

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

17 SEP 2020 22:37

PC Open Date & Time

17 SEP 2020 18:10

PC Close Date & Time

18 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 19:23

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:29

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:08

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:08

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	23 SEP 2020 19:28
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:04
PC Open Date & Time	17 SEP 2020 14:45
PC Close Date & Time	17 SEP 2020 17:15

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 22:38
PC Open Date & Time	17 SEP 2020 18:10
PC Close Date & Time	18 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 2984

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	18 SEP 2020 19:26
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2984

EAB) (1725)

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	19 SEP 2020 21:18
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 ☒

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003

60 of 2984

EAB) (1725)

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	21 SEP 2020 21:09
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003

62 of 2984

EAB) (1725)

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	22 SEP 2020 22:09
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

64 of 2984

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	23 SEP 2020 19:28
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3602051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:44

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:44

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:43
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 15:55
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	FOREHEAD/TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 15:25

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

US3602051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

13:43 (24 HR)

Collection date and time (derived)

14 OCT 2020 13:43

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:43	14 OCT 2020 13:43
Nasopharyngeal Swab 2	No		

US3602051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 15:55

PC Open Date & Time

14 OCT 2020 15:45

PC Close Date & Time

14 OCT 2020 18:15

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 98.7 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 14 OCT 2020 20:09

PC Open Date & Time 14 OCT 2020 19:10

PC Close Date & Time 15 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

15 OCT 2020 14:51

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 18:16

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 21:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 18:35

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 19:28

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

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.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 19:44

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 15:56

PC Open Date & Time

14 OCT 2020 15:45

PC Close Date & Time

14 OCT 2020 18:15

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

14 OCT 2020 20:12

PC Open Date & Time

14 OCT 2020 19:10

PC Close Date & Time

15 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 14:52

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 18:17

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 21:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 18:35

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 19:29

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 19:44

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 15:56
PC Open Date & Time	14 OCT 2020 15:45
PC Close Date & Time	14 OCT 2020 18:15

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 20:14
PC Open Date & Time	14 OCT 2020 19:10
PC Close Date & Time	15 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 2984

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	15 OCT 2020 14:52
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2984

EAB) (1725)

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	16 OCT 2020 18:17
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

104 of 2984

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	17 OCT 2020 21:06
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

106 of 2984

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	18 OCT 2020 18:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003

108 of 2984

EAB) (1725)

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	19 OCT 2020 19:29
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

110 of 2984

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

Yes ☐	
PC Time stamp	20 OCT 2020 19:45
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 21 OCT 2020 18:50

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 22 OCT 2020 18:24

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 23 OCT 2020 22:07

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 OCT 2020 18:41

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 OCT 2020 20:24

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 OCT 2020 20:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 OCT 2020 18:50
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 OCT 2020 18:24
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 OCT 2020 22:07
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 OCT 2020 18:41
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 OCT 2020 20:24
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

26 OCT 2020 20:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 15

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3602051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:14:46

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:14:46

Generated On: 10 Jun 2021 09:10:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 12:28
Temperature (xxx.x)	96.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	FOREHEAD/TEMPORAL
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3602051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	12:28 (24 HR)
Collection date and time (derived)	11 NOV 2020 12:28

US3602051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:14:45

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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 NOV 2020 09:38:34

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

DAY 68

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 19:47:28

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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	28 NOV 2020 10:01:10
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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	05 DEC 2020 13:00:45
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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

12 DEC 2020 00:07:22

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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 DEC 2020 00:28:06

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

26 DEC 2020 21:53:01

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒ 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 JAN 2021 01:29:21
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

09 JAN 2021 01:59:39

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

16 JAN 2021 21:50:39

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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

23 JAN 2021 00:02:18

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

30 JAN 2021 12:38:57

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒ 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 FEB 2021 01:11:46
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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

13 FEB 2021 00:31:39

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

20 FEB 2021 01:39:09

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

01 MAR 2021 00:25:35

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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 MAR 2021 00:35:15

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

13 MAR 2021 00:22:02

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

20 MAR 2021 12:45:55

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

27 MAR 2021 14:53:53

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

03 APR 2021 14:26:32

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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

10 APR 2021 19:49:15

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

18 APR 2021 14:14:56

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

24 APR 2021 00:02:34

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☒

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

01 MAY 2021 01:15:14

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAR 2022 00:01

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30 MAR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUN 2022 00:01

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29 JUN 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUL 2022 00:01

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06 JUL 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUL 2022 00:01

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13 JUL 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUL 2022 00:01

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20 JUL 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUL 2022 00:01

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27 JUL 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 JUL 2022 00:01

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03 AUG 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 AUG 2022 00:01

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10 AUG 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 AUG 2022 00:01

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24 AUG 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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°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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3602051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:10:45

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		01 MAR 2021 00:26:06

US3602051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

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

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:02:20

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:02:20

Generated On: 10 Jun 2021 09:10:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:24
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3602051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	13:30 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:30

US3602051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3602051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:10:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3602051

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	18 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3602051

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Date of updated informed consent (dd MMM yyyy)	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (dd MMM yyyy)	18 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3602051

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3602051

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 13:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	15:24 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 15:24
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3602051

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

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) 18 JAN 2021

What was the treatment time? (00:00-23:59) 14:54 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 14:54

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

US3602051

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

18 JAN 2021 13:30

US3602051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	13:25
Collection Date and Time (derived)	18 JAN 2021 13:25

US3602051

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3602051

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 12:15
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 14:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
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)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3602051

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3602051

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 13:35

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

US3602051

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602051

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602051

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:24
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602051

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3602051

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	13:30 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:30

US3602051

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

AEID

Adverse event

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)

14 OCT 2020

Start time (00:00-23:59)

18:00 (24 HR)

AE start date and time (derived)

14 OCT 2020 18:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 OCT 2020

End time (00:00-23:59)

21:00 (24 HR)

AE End Date and Time (derived)

14 OCT 2020 21:00

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

369 of 2984

EAB) (1725)

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

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)	_____ _____

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

AEID	USA-US079-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING OF AORTIC STENOSIS
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)	28 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)	2 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	True
Hospital Admission Date (dd MMM yyyy)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	2 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
PRODUCTION RELEASE (v12.003 EAB) (1725)	371 of 2984

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

Number of Days in ICU	2
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	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:	PT WITH OPEN SURGERY AND POST OP RECOVERY ONGOING
Narrative	

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE -- RELEVANT PROCEDURES/DIAGNOSTIC TESTS: ECHO 10/19 @ 1623: LEFT VENTRICLE: NORMAL LEFT VENTRICULAR SYSTOLIC FUNCTION. EJECTION FRACTION ESTIMATED AT 65 - 70%. GRADE 1 (MILD) LV DIASTOLIC DYSFUNCTION. MODERATE CONCENTRIC HYPERTROPHY. LEFT ATRIUM: LEFT ATRIUM IS MILDLY DILATED AORTIC VALVE: A BICUSPID VALVE CANNOT BE EXCLUDED. THERE

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

IS CALCIFICATION OF THE
AORTIC VALVE PRESENT.
SEVERE STENOSIS. TRACE
REGURGITATION ON
COLOR-FLOW PW DOPPLER.
AV PEAK GRADIENT:
107.0MMHG AV MEAN
GRADIENT: 82.0MMHG AORTIC
VALVE AREA: 0.49CM2
PULMONIC VALVE: TRACE
REGURGITATION ON
COLOR-FLOW PW DOPPLER.

--- EKG: 10/27/2020 -
ABNORMAL, 10/29/2020 -
ABNORMAL,
10/30/2020 - ABNORMAL

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)	1

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

AEID	USA-US079-2020-MRNA-1273-P30 1000004
Adverse event	INCREASED BLEEDING INTRA OPERATIVE TIME
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)	29 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)	29 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 EAB) (1725)	375 of 2984

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

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	

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

PT UNDERWENT AVR AND WAS
NOTED TO BLEED PROFUSELY
AND THE SURGEON FELT THAT
THAT THERE WAS NO KNOWN
CAUSE OF THE SAME AND
RAISED THE POSSIBILITY OF
ASSOCIATION OF THE
BLEEDING RISK WITH THE USE
OF A STUDY PRODUCT.
SUBJECT WAS TAKING THE
FOLLOWING CONMEDS ON AN
ONGOING BASIS PRIOR TO AVR
SURGERY: MULTIVITAMIN
(CENTRAVITE WITH
ANTIOXIDANTS)
VITAMIN D1,
ZINC,
NICOTROL,
INCRUSE (UMECLINIDIUM)
ATORVASTATIN,
MOTRIN (IBUPROFEN),
VITAMIN C,
FISH OIL
ALBUTEROL SULFATE. --
SUBJECT TOOK/WAS
ADMINISTERED THE
FOLLOWING MEDICATIONS
AFTER BEING ADMITTED TO
THE HOSPITAL, BETWEEN THE
DAY PRIOR TO SURGERY
(28OCT2020) AND THE END OF
AVR SURGERY:
DIPHENHYDRAMINE
(BENADRYL),
DIAZEPAM

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

(VALIUM)
ASPIRIN,
FENTANYL (SUBLIMAZE)
,MIDAZOLAM (VERSED),
METOPROLOL TARTRATE
(LOPRESSOR),
ACETAMINOPHEN (TYLENOL).
RELEVANT LAB TEST RESULTS
ARE AS FOLLOW: (1)PTT (12.2 -
14.4 SECONDS): 10/28/20 = 14.6,
10/29/20 = 17.9, 10/30/20 = 15.1; (2)
INR (0.80 - 1.20): 10/28/20 = 1.16,
10/29/20 = 1.52, 10/30/20 = 1.21;
(3) PTT (23.4 - 38.9 SECS):
10/28/20 = 29.9, 10/29/20 = ND,
10/30/20 = 33.7; (4)HGB (13.0 - 17.0
GM/DL): 10/28/20 = ND, 10/29/20 =
8.8, 10/30/20 = 8.8; (5)HCT (38.7 -
50.0 %): 10/28/20 = ND, 10/29/20 =
24.7, 10/30/20 = 25.1; (6)PLT (135 -
430 X10(3)/MCL): 10/28/20 = ND,
10/29/20 = 127, 10/30/20 = 142

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)	1

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

AEID

Adverse event

RIB 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 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)

31 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

379 of 2984

EAB) (1725)

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 22:09:32

Generated On: 10 Jun 2021 09:10:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

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

Yes ☒

No ☐

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

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication NICOTROL

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication INCRUSE (UMECLINIDIUM)

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 62.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HLD

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 800

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

PRN, 1-2X/MONTH

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	UN JUL 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MOTRIN (IBUPROFEN)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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)

390 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ACETAMINOPHEN (OFIRMEV)

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL R/T AVR
SURGERY DUE TO SAE
WORSENING OF AORTIC
STENOSIS

Dose per administration 1,000

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

Q6H (2 DOSES TOTAL)

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ACETAMINOPHEN (TYLENOL)

Prophylaxis Yes ☐
No ☒

Indication PAIN (MUSCULOSKELETAL
AND CONNECTIVE TISSUE
RELATED CHEST PAIN DUE TO
AVR SURGERY RELATED
INCISION)

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	29 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 ☐	

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication APIXABAN (ELIQUIS)

Prophylaxis Yes ☒
No ☐

Indication NON-VALVULAR ATRIAL
FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify Q12H

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ASPIRIN (TABLET)

Prophylaxis Yes ☐
No ☒

Indication UNK (TAKEN PRIOR TO ATRIAL
VALVE REPLACEMENT
SURGERY)

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 28 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ASPIRIN (ECOTRIN)

Prophylaxis Yes ☐
No ☒

Indication S/P CARDIAC SURGERY

Dose per administration 81

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 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication AZTREONAM (AZACTAM) / D5W

Prophylaxis Yes ☒
No ☐

Indication ANTI-BIOTIC (SURGICAL
PROPHYLAXIS)

Dose per administration 1/50

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

If dose unit is Other, specify G/ML

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 Q8H

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	31 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication BACITRACIN (OINTMENT)

Prophylaxis Yes ☒
No ☐

Indication INCISION CARE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 NOV 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication DIPHENHYDRAMINE
(BENADRYL)

Prophylaxis Yes ☒
No ☐

Indication INSOMNIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

THREE TIMES

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication FENTANYL (SUBLIMAZE)

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL (RVA SURGERY)

Dose per administration 0.05

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

TWO (2) TIMES

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication FERROUS SULFATE 325 (65 FE)
MG TABLET

Prophylaxis Yes ☐
No ☒

Indication ANEMIA FROM INADEQUATE
IRON IN THE BODY (S/P AVR)

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		2 NOV 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	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication KETOROLAC (TORADOL)

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL (S/P RVA SURGERY)

Dose per administration 15

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)

412 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	31 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MEPERIDINE (DEMEROL)

Prophylaxis Yes ☐
No ☒

Indication SHIVERING (S/P RVA SURGERY)

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

TWO (2) TIMES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	29 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 ☐	

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication METOPROLOL TARTRATE
(LOPRESSOR)

Prophylaxis Yes ☒
No ☐

Indication R/T TO RVA SURGERY

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MIDAZOLAM (VERSED) 10
MG/2ML

Prophylaxis Yes ☐
No ☒

Indication SEDATION (R/T RVA SURGERY)

Dose per administration 10/2

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

If dose unit is Other, specify MG/ML

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)

418 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication MODERATE PAIN (R/T RVA SURGERY)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

420 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication SEVERE PAIN (8-10) R/T RVA
SURGERY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ONDANSETRON (ZOFTRAN)
INJECTION

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
NAUSEA/VOMITING (S/P AVR
SURGERY)

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6H, PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication OXYCODONE IMMEDIATE
RELEASE (ROXICODONE)

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		2 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication PROCHLORPERAZINE
EDISYLATE (COMPAZINE)

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN (ADMINISTERED
DURING RVA SURGERY)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication TRAMADOL (ULTRAM)

Prophylaxis Yes ☐
No ☒

Indication MODERATE PAIN (4-7) IN CHEST
R/T S/P AVR SURGERY DUE TO
WORSENING OF AORTIC
STENOSIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	2 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication VANCOMYCIN (VANCOCIN) 1 G
IN D5W (5% SOLN) 250 ML

Prophylaxis Yes ☒
No ☐

Indication ANTI-BIOTIC TO PREVENT
INFECTION R/T ARV SURGERY
DUE TO WORSENING OF
AORTIC STENOSIS

Dose per administration 1/250

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

If dose unit is Other, specify G/ML

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 Q12H

Route of administration Oral ☐
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	30 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 ☐	

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication WARFARIN (COUMADIN)

Prophylaxis Yes ☒
No ☐

Indication ANTICOAGULANT (S/P AVR SURGERY)

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

434 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		31 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication WARFARIN (COUMADIN)

Prophylaxis Yes ☒
No ☐

Indication ANTICOAGULANT (S/P AVR SURGERY)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

436 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		1 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes ☐
No ☒

Indication COPD
EXACERBATION/WHEEZING

Dose per administration 90

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)

438 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication DIAZEPAM (VALIUM)

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

440 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 28 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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL GOOD HEALTH

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)

442 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication GENERAL GOOD HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication MULTIVITAMIN (CENTRAVITE
WITH ANTIOXIDANTS)

Prophylaxis Yes ☒
No ☐

Indication GENERAL 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

446 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
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	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication VITAMIN D1

Prophylaxis Yes ☒
No ☐

Indication GENERAL GOOD HEALTH

Dose per administration 5000

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)

448 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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	☐

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication GENERAL GOOD HEALTH

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

450 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 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)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication GENITAL HERPES (OUTBREAK)

Dose per administration 800

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)

452 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

Name of Medication SIMVASTATIN (ZOCOR)

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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)

454 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 05 Apr 2021 21:02:19

Generated On: 10 Jun 2021 09:10:45

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 NOV 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	☒

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 22:09:34

Generated On: 10 Jun 2021 09:10:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	AORTIC VALVE REPLACEMENT SURGERY	Adverse Event	
19 OCT 2020	COLOR-FLOW PW ECHOCARDIOGRAM	Diagnostic	
27 OCT 2020	ELECTROCARDIOGRAM (EKG)	Diagnostic	
28 OCT 2020	CARDIAC CATHETERIZATION	Adverse Event	
2 NOV 2020	PHYSICAL THERAPY (FOLLOWING AVR SURGERY PRIOR TO DISCHARGE)	Adverse Event	
28 OCT 2020	PHYSICAL THERAPY (PRIOR TO AVR SURGERY)	Adverse Event	
29 OCT 2020	BLOOD/PLATELET/CRYOPRECIPITATE TRANSFUSION (INTRAOPERATIVE, AVR SURGERY)	Adverse Event	
29 OCT 2020	ELECTROCARDIOGRAM (EKG)	Diagnostic	
30 OCT 2020	ELECTROCARDIOGRAM (EKG)	Diagnostic	

US3602051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:45

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

US3602051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:45

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 ☐

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	18/NOV/2020 10:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:31
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

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	20/NOV/2020 11:26
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

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	02/DEC/2020 08:12
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

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 22:09:39

Generated On: 10 Jun 2021 09:10:45

SAEID	USA-US079-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	08/JAN/2021 16:36
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

Audit

US3602051 (Prod: Hackensack University Medical Center)

US3602051

Form: Participant Creation

Generated On: 10 Jun 2021 09:10:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:41:10
User entered 'US3602051'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:45:20

US3602051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:07:51

US3602051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:45:21

US3602051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:07:51

US3602051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'SCRN'	System	17 Sep 2020 16:07:51

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:45:22

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '52'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'YEARS'	System	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '52'	System	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User closed query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:05:34
Query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' answered with 'Data has been updated.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 17:12:15
User opened query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 13:13:25
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:11:50
User entered 'Hispanic' reason for change: New Information	(b) (4), (b) (6)	20 Apr 2021 17:11:50
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Other Race' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:57
User entered 'Hispanic'	(b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:25

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Sep 2020'	System	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2020'	System	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:53

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:45:21

US3602051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '1'	System	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:10:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:50:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:54:51
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 17:43:39

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User closed query 'Per MM: Please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:18:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:38:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:38:33
Data point term sent to Coder	System	05 Oct 2020 17:37:17
Query 'Per MM: Please expand the abbreviation. ' answered with 'Chronic obstructive pulmonary disease' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:37:03
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 17:36:57
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:36:57
User opened query 'Per MM: Please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:57:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:59:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:59:38
Data point term sent to Coder	System	17 Sep 2020 17:58:33
User entered 'COPD'	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2015'	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2015'	System	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2015'	System	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:58:03

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:00:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:00:39
Data point term sent to Coder	System	17 Sep 2020 17:59:36
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2008'	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2008'	System	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2008'	System	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:59:10

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Headache tension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 12:34:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 12:34:30
Data point term sent to Coder	System	05 Nov 2020 21:29:04
User entered 'HEADACHES (Type: tension)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:28:32
Data point term sent to Coder	System	05 Nov 2020 21:28:02
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 21:27:11
User entered 'Tension HEADACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:27:11
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)	17 Sep 2020 18:01:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:01:41
Data point term sent to Coder	System	17 Sep 2020 18:00:37
User entered 'Headaches'	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 19:02:25
User entered 'UN UNK 2010'	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2005'	System	02 Dec 2020 19:02:25
User entered 'Jan 2010'	System	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2005'	System	02 Dec 2020 19:02:25
User entered '2010'	System	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	17 Sep 2020 17:59:54

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:18:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:18:55
Data point term sent to Coder	System	23 Sep 2020 01:52:25
User entered 'Bronchitis (mild)'	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2015'	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2015'	System	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2015'	System	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	23 Sep 2020 01:52:24

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:53:44
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 'Arthritis ' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 21:49:10
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:09:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 01:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 01:54:52
Data point term sent to Coder	System	23 Sep 2020 01:54:26
User entered 'Knee Replacement'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2012'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2012'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2012'	System	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2012'	System	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2012'	System	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2012'	System	23 Sep 2020 01:53:56

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Social circumstances, HLGt: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:53:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:53:25
Data point term sent to Coder	System	05 Nov 2020 20:52:59
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 20:52:09
User entered 'SMOKing' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:52:09
User coded data point as SOC: Social circumstances, HLGt: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:14:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:14:20
Data point term sent to Coder	System	05 Nov 2020 18:13:52
User entered 'Smoker'	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2000' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 21:43:42
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 21:43:42
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN Mar 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:52:09
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:52:09
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2000'	System	30 Nov 2020 21:43:42
User entered empty.	System	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2000'	System	30 Nov 2020 21:43:42
User entered empty.	System	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Mar 2020'	System	05 Nov 2020 20:52:09
User entered empty.	System	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2020'	System	05 Nov 2020 20:52:09
User entered empty.	System	05 Nov 2020 18:12:54

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4)	20 Jan 2021 15:45:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Jan 2021 15:45:04
Data point term sent to Coder	System	20 Jan 2021 15:44:20
User entered 'AORTIC STENOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:43:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 15:43:26
Coding entries removed.	(b) (4), (b) (6)	20 Jan 2021 15:43:26
User entered 'Severe AORTIC STENOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:43:26
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 15:54:41
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4)	27 Nov 2020 18:25:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Nov 2020 18:25:11
Data point term sent to Coder	System	27 Nov 2020 18:24:08
Coding entries removed.	(b) (4), (b) (6)	27 Nov 2020 18:23:41
User entered 'AORTIC STENOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 18:23:41
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 04:50:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 04:50:39
Data point term sent to Coder	System	05 Nov 2020 21:24:50

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 21:23:52
User entered 'AORTIC STENOSIS (diagnosed in 2020, previously reported as non-specific murmur a few years ago)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:23:52
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:16:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:16:46
Data point term sent to Coder	System	05 Nov 2020 21:15:15
User entered 'Aortic Stenosis'	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	20 Jan 2021 15:43:59
User entered 'UN UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:43:59
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	20 Jan 2021 15:43:26
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 15:43:26
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:43:26
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 18:23:41
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Nov 2020 21:24:08
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Nov 2020 21:23:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:23:52
User entered 'UN UNK 2020'	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 18:23:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:24:08
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:48:58
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	20 Jan 2021 15:46:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:46:32
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	20 Jan 2021 15:45:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:45:42
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 15:44:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:44:48
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:48:58
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Jan 2021 15:46:32
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:46:32
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Jan 2021 15:44:48
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 15:44:48
User entered '24 Sep 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 15:44:48
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2020'	System	20 Jan 2021 15:43:59
User entered 'Sep 2020'	System	20 Jan 2021 15:43:26
User entered 'Jan 2020'	System	27 Nov 2020 18:23:41
User entered empty.	System	05 Nov 2020 21:23:52
User entered 'Jan 2020'	System	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2020'	System	27 Nov 2020 18:23:41
User entered empty.	System	05 Nov 2020 21:23:52
User entered '2020'	System	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	20 Jan 2021 15:48:58
User entered 'Sep 2020'	System	20 Jan 2021 15:46:32
User entered 'Sep 2019'	System	20 Jan 2021 15:44:48
User entered empty.	System	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	20 Jan 2021 15:48:58
User entered '2020'	System	20 Jan 2021 15:46:32
User entered '2019'	System	20 Jan 2021 15:44:48
User entered empty.	System	05 Nov 2020 21:14:58

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Arthritis multiple joint - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:35:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:35:29
Data point term sent to Coder	System	06 Nov 2020 06:34:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Arthritis multiple joint - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:34:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:34:30
Query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)ARTHRITIS KNEES BILATERALLY, 2)ARTHRITIS NECK' canceled (Site from System).	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:34:30
User opened query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)ARTHRITIS KNEES BILATERALLY, 2)ARTHRITIS NECK' (Site from System).	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:01:33
Data point term sent to Coder	System	05 Nov 2020 21:27:00
User entered 'Arthritis (Type: unknown; Location: Knees bilaterally, neck)'	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2011'	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2011'	System	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2011'	System	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	05 Nov 2020 21:26:05

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:31:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:31:18
Data point term sent to Coder	System	06 Nov 2020 14:46:58
User entered 'Syncope (recurrent)'	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2018' reason for change:	(b) (4), (b) (6)	02 Dec 2020 19:01:16
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	02 Dec 2020 19:01:25
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 19:01:25
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	02 Dec 2020 19:01:16
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2018'	System	02 Dec 2020 19:01:16
User entered empty.	System	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2018'	System	02 Dec 2020 19:01:16
User entered empty.	System	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	06 Nov 2020 14:46:28

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:10:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:10:03
Data point term sent to Coder	System	18 Nov 2020 23:33:01
User entered 'Genital herpes (last outbreak July 2020)'	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 2012' reason for change:	(b) (4), (b) (6)	02 Dec 2020 19:01:58
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 19:01:58
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 2012'	System	02 Dec 2020 19:01:58
User entered empty.	System	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '2012'	System	02 Dec 2020 19:01:58
User entered empty.	System	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	18 Nov 2020 23:32:49

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 18:35:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 18:35:11
Data point term sent to Coder	System	27 Nov 2020 18:25:08
User entered 'NON-SPECIFIC Cardiac MURMUR (diagnosed A FEW YEARS AGO)'	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '1'	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered empty.	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered empty.	System	27 Nov 2020 18:24:34

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 21:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 21:47:37
Data point term sent to Coder	System	30 Nov 2020 21:45:49
User entered 'Rotator Cuff tear (right)'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 1996'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 1996'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 1996'	System	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '1996'	System	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 1996'	System	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '1996'	System	30 Nov 2020 21:45:48

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:36:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:36:25
Data point term sent to Coder	System	30 Nov 2020 21:47:51
User entered 'Rotator cuff repair (right)'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 1996'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered 'UN UNK 1996'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:54
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 1996'	System	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '1996'	System	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'Jan 1996'	System	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '1996'	System	30 Nov 2020 21:47:07

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11:51'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '69' in	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24
DataPoint set to visible.	System	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '152' lb	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24
DataPoint set to visible.	System	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered '22.49341'	System	17 Sep 2020 17:45:24
DataPoint set to visible.	System	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'kg/m2'	System	17 Sep 2020 17:45:24
DataPoint set to visible.	System	17 Sep 2020 16:13:01

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'bpm'	System	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'breaths/min'	System	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'mmHg'	System	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User entered 'mmHg'	System	17 Sep 2020 17:45:24

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42

US3602051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42

US3602051

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:05

US3602051

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:05

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:47:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:47:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:47:34
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'out of work on disability' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 18:01:31
User entered 'UNKNOWN'	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:42
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:34

US3602051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:23

US3602051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:23

US3602051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:23

US3602051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'VISIT1'	System	17 Sep 2020 17:28:23

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:32

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '146508'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:32

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:32

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:33

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:33

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:33

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:48:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:48:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:48:40
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:48:33
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:48:33

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:33

US3602051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:56:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:25:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:25:23

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '69' in	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '152' lb	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '69' in	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '152' lb	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11:51'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '86'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'bpm'	System	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '12'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'breaths/min'	System	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '120'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '86'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '69' in	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:57:06
User entered '152' lb	(b) (4), (b) (6)	17 Sep 2020 17:31:19

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14:55'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '17 Sep 2020 14:55'	System	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '63'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'bpm'	System	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '12'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'breaths/min'	System	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '122'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	17 Sep 2020 19:32:12

US3602051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	17 Sep 2020 17:32:58
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	17 Sep 2020 17:32:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:31:40

US3602051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:32:58
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:31:40

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14:25'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '17 Sep 2020 14:25'	System	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'ONCE'	System	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 18:29:59

US3602051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:41

US3602051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:41

US3602051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11:51'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:41

US3602051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 17:33:41

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Per GCL Lab Reconciliation: Swab re-query: Please confirm if unscheduled lab kit was used for visit 1 day 1 and provide the accession number used for visit 1 day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:42:56
Query 'Per GCL Lab Reconciliation: Swab re-query: Please confirm if unscheduled lab kit was used for visit 1 day 1 and provide the accession number used for visit 1 day 1.' answered with 'Confirming that Visit 1 Day 1 NP Swab from an Unscheduled Visit Lab Kit was used. The accession number for Visit 1 Day 1 is 1F640869890' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:12:11
User opened query 'Per GCL Lab Reconciliation: Swab re-query: Please confirm if unscheduled lab kit was used for visit 1 day 1 and provide the accession number used for visit 1 day 1.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 01:20:40
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is recorded under Visit 1 Day 1 visit in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 01:20:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is recorded under Visit 1 Day 1 visit in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'not applicable' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 21:52:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is recorded under Visit 1 Day 1 visit in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:02:14
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11:51'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered empty.	System	17 Sep 2020 17:34:23

US3602051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:35

US3602051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	17 Sep 2020 17:34:35

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:01:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9b6cd5a0-f5be-4a62-878b-2e561030652b'	System	17 Sep 2020 19:02:49
User entered 'Yes (Y)'	System	17 Sep 2020 19:02:49

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:02:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9b6cd5a0-f5be-4a62-878b-2e561030652b'	System	17 Sep 2020 19:02:49
User entered '97.7'	System	17 Sep 2020 19:02:49

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:02:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9b6cd5a0-f5be-4a62-878b-2e561030652b'	System	17 Sep 2020 19:02:49
User entered 'No (N)'	System	17 Sep 2020 19:02:49

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:02:22', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9b6cd5a0-f5be-4a62-878b-2e561030652b'	System	17 Sep 2020 19:02:49
User entered '17 Sep 2020 15:02'	System	17 Sep 2020 19:02:49

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 14:45'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 17:15'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:15', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c6b1f3e1-1bc3-4397-8c10-2cef5bd2b00a'	System	18 Sep 2020 02:37:27
User entered 'Yes (Y)'	System	18 Sep 2020 02:37:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c6b1f3e1-1bc3-4397-8c10-2cef5bd2b00a' User entered '97.0'	System	18 Sep 2020 02:37:27
	System	18 Sep 2020 02:37:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c6b1f3e1-1bc3-4397-8c10-2cef5bd2b00a'	System	18 Sep 2020 02:37:27
User entered 'No (N)'	System	18 Sep 2020 02:37:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c6b1f3e1-1bc3-4397-8c10-2cef5bd2b00a'	System	18 Sep 2020 02:37:27
User entered '17 Sep 2020 22:37'	System	18 Sep 2020 02:37:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 18:10'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 2'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:21:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a115656b-f4fc-4c4e-965d-eb0322318426'	System	18 Sep 2020 23:22:13
User entered 'Yes (Y)'	System	18 Sep 2020 23:22:13

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:21:22', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a115656b-f4fc-4c4e-965d-eb0322318426'	System	18 Sep 2020 23:22:13
User entered '98.5'	System	18 Sep 2020 23:22:13

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:21:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a115656b-f4fc-4c4e-965d-eb0322318426'	System	18 Sep 2020 23:22:13
User entered 'No (N)'	System	18 Sep 2020 23:22:13

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:22:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a115656b-f4fc-4c4e-965d-eb0322318426'	System	18 Sep 2020 23:22:13
User entered '18 Sep 2020 19:22'	System	18 Sep 2020 23:22:13

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 3'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:15:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f5787545-3674-4108-8956-146090c7ba1d'	System	20 Sep 2020 01:16:21
User entered 'Yes (Y)'	System	20 Sep 2020 01:16:21

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:15:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f5787545-3674-4108-8956-146090c7ba1d' User entered '97.8'	System	20 Sep 2020 01:16:21
	System	20 Sep 2020 01:16:21

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f5787545-3674-4108-8956-146090c7ba1d'	System	20 Sep 2020 01:16:21
User entered 'No (N)'	System	20 Sep 2020 01:16:21

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f5787545-3674-4108-8956-146090c7ba1d' User entered '19 Sep 2020 21:16'	System	20 Sep 2020 01:16:21
	System	20 Sep 2020 01:16:21

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 4'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:28:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '85b905e2-f19a-4871-8887-878792d5bb28'	System	21 Sep 2020 00:28:56
User entered 'Yes (Y)'	System	21 Sep 2020 00:28:56

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:28:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '85b905e2-f19a-4871-8887-878792d5bb28' User entered '98.7'	System	21 Sep 2020 00:28:56
	System	21 Sep 2020 00:28:56

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:28:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '85b905e2-f19a-4871-8887-878792d5bb28'	System	21 Sep 2020 00:28:56
User entered 'No (N)'	System	21 Sep 2020 00:28:56

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:28:59', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '85b905e2-f19a-4871-8887-878792d5bb28'	System	21 Sep 2020 00:28:56
User entered '20 Sep 2020 20:28'	System	21 Sep 2020 00:28:56

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 5'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '463ae99e-632d-402a-9ea3-b054f4ab90a0'	System	22 Sep 2020 01:07:39
User entered 'Yes (Y)'	System	22 Sep 2020 01:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:30', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '463ae99e-632d-402a-9ea3-b054f4ab90a0'	System	22 Sep 2020 01:07:39
User entered '98.7'	System	22 Sep 2020 01:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '463ae99e-632d-402a-9ea3-b054f4ab90a0'	System	22 Sep 2020 01:07:39
User entered 'No (N)'	System	22 Sep 2020 01:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '463ae99e-632d-402a-9ea3-b054f4ab90a0'	System	22 Sep 2020 01:07:39
User entered '21 Sep 2020 21:07'	System	22 Sep 2020 01:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 6'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:06:57', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '45c8c5a4-a0c8-4c51-8ace-4b917b81279f'	System	23 Sep 2020 02:07:39
User entered 'Yes (Y)'	System	23 Sep 2020 02:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:07:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '45c8c5a4-a0c8-4c51-8ace-4b917b81279f' User entered '96.8'	System	23 Sep 2020 02:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:07:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '45c8c5a4-a0c8-4c51-8ace-4b917b81279f'	System	23 Sep 2020 02:07:39
User entered 'No (N)'	System	23 Sep 2020 02:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:07:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '45c8c5a4-a0c8-4c51-8ace-4b917b81279f'	System	23 Sep 2020 02:07:39
User entered '22 Sep 2020 22:07'	System	23 Sep 2020 02:07:39

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 7'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ca36b37a-9426-43f8-9656-0e37ef66b509'	System	23 Sep 2020 23:27:27
User entered 'Yes (Y)'	System	23 Sep 2020 23:27:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ca36b37a-9426-43f8-9656-0e37ef66b509'	System	23 Sep 2020 23:27:27
User entered '99.1'	System	23 Sep 2020 23:27:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ca36b37a-9426-43f8-9656-0e37ef66b509'	System	23 Sep 2020 23:27:27
User entered 'No (N)'	System	23 Sep 2020 23:27:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ca36b37a-9426-43f8-9656-0e37ef66b509'	System	23 Sep 2020 23:27:27
User entered '23 Sep 2020 19:27'	System	23 Sep 2020 23:27:27

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:02:41', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c5651b9e-70d0-4f03-8e2e-99e5012cdf23'	System	17 Sep 2020 19:03:59
User entered 'None (1)'	System	17 Sep 2020 19:03:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:02:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c5651b9e-70d0-4f03-8e2e-99e5012cdf23'	System	17 Sep 2020 19:03:59
User entered 'No (N)'	System	17 Sep 2020 19:03:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c5651b9e-70d0-4f03-8e2e-99e5012cdf23'	System	17 Sep 2020 19:03:59
User entered 'No (N)'	System	17 Sep 2020 19:03:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:21', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c5651b9e-70d0-4f03-8e2e-99e5012cdf23'	System	17 Sep 2020 19:03:59
User entered 'None (1)'	System	17 Sep 2020 19:03:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c5651b9e-70d0-4f03-8e2e-99e5012cdf23'	System	17 Sep 2020 19:03:59
User entered '17 Sep 2020 15:03'	System	17 Sep 2020 19:03:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 14:45'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 17:15'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '74adffc7-21fd-473f-90dc-22864a0aa991'	System	18 Sep 2020 02:37:58
User entered 'None (1)'	System	18 Sep 2020 02:37:58

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '74adffc7-21fd-473f-90dc-22864a0aa991'	System	18 Sep 2020 02:37:58
User entered 'No (N)'	System	18 Sep 2020 02:37:58

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '74adffc7-21fd-473f-90dc-22864a0aa991'	System	18 Sep 2020 02:37:58
User entered 'No (N)'	System	18 Sep 2020 02:37:58

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '74adffc7-21fd-473f-90dc-22864a0aa991'	System	18 Sep 2020 02:37:58
User entered 'None (1)'	System	18 Sep 2020 02:37:58

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:37:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '74adffc7-21fd-473f-90dc-22864a0aa991'	System	18 Sep 2020 02:37:58
User entered '17 Sep 2020 22:37'	System	18 Sep 2020 02:37:58

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 18:10'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 2'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:22:43', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '085c5ca9-0c7e-44a3-95ff-e45757888679'	System	18 Sep 2020 23:23:55
User entered 'None (1)'	System	18 Sep 2020 23:23:55

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:22:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '085c5ca9-0c7e-44a3-95ff-e45757888679'	System	18 Sep 2020 23:23:55
User entered 'No (N)'	System	18 Sep 2020 23:23:55

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:23:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '085c5ca9-0c7e-44a3-95ff-e45757888679'	System	18 Sep 2020 23:23:55
User entered 'No (N)'	System	18 Sep 2020 23:23:55

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:23:41', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '085c5ca9-0c7e-44a3-95ff-e45757888679'	System	18 Sep 2020 23:23:55
User entered 'None (1)'	System	18 Sep 2020 23:23:55

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:23:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '085c5ca9-0c7e-44a3-95ff-e45757888679'	System	18 Sep 2020 23:23:55
User entered '18 Sep 2020 19:23'	System	18 Sep 2020 23:23:55

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 3'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'aab65877-81ec-4872-ae8b-4bb4d6ec5f10'	System	20 Sep 2020 01:16:59
User entered 'None (1)'	System	20 Sep 2020 01:16:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'aab65877-81ec-4872-ae8b-4bb4d6ec5f10'	System	20 Sep 2020 01:16:59
User entered 'No (N)'	System	20 Sep 2020 01:16:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'aab65877-81ec-4872-ae8b-4bb4d6ec5f10'	System	20 Sep 2020 01:16:59
User entered 'No (N)'	System	20 Sep 2020 01:16:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:52', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'aab65877-81ec-4872-ae8b-4bb4d6ec5f10'	System	20 Sep 2020 01:16:59
User entered 'None (1)'	System	20 Sep 2020 01:16:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:16:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'aab65877-81ec-4872-ae8b-4bb4d6ec5f10'	System	20 Sep 2020 01:16:59
User entered '19 Sep 2020 21:16'	System	20 Sep 2020 01:16:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 4'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:29:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '15dafe0f-1c42-47fc-a41c-177822ffd586'	System	21 Sep 2020 00:29:47
User entered 'None (1)'	System	21 Sep 2020 00:29:47

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:29:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '15dafe0f-1c42-47fc-a41c-177822ffd586'	System	21 Sep 2020 00:29:47
User entered 'No (N)'	System	21 Sep 2020 00:29:47

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:29:37', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '15dafe0f-1c42-47fc-a41c-177822ffd586'	System	21 Sep 2020 00:29:47
User entered 'No (N)'	System	21 Sep 2020 00:29:47

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:29:46', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '15dafe0f-1c42-47fc-a41c-177822ffd586'	System	21 Sep 2020 00:29:47
User entered 'None (1)'	System	21 Sep 2020 00:29:47

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:29:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '15dafe0f-1c42-47fc-a41c-177822ffd586'	System	21 Sep 2020 00:29:47
User entered '20 Sep 2020 20:29'	System	21 Sep 2020 00:29:47

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 5'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '30e9fdf9-fb80-410b-8730-31b8f5962a8a'	System	22 Sep 2020 01:08:09
User entered 'None (1)'	System	22 Sep 2020 01:08:09

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '30e9fdf9-fb80-410b-8730-31b8f5962a8a'	System	22 Sep 2020 01:08:09
User entered 'No (N)'	System	22 Sep 2020 01:08:09

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:07:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '30e9fdf9-fb80-410b-8730-31b8f5962a8a'	System	22 Sep 2020 01:08:09
User entered 'No (N)'	System	22 Sep 2020 01:08:09

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '30e9fdf9-fb80-410b-8730-31b8f5962a8a'	System	22 Sep 2020 01:08:09
User entered 'None (1)'	System	22 Sep 2020 01:08:09

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '30e9fdf9-fb80-410b-8730-31b8f5962a8a'	System	22 Sep 2020 01:08:09
User entered '21 Sep 2020 21:08'	System	22 Sep 2020 01:08:09

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 6'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:07:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '2e672584-ab66-42e1-8829-4d9625b2713b'	System	23 Sep 2020 02:08:24
User entered 'None (1)'	System	23 Sep 2020 02:08:24

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:07:50', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '2e672584-ab66-42e1-8829-4d9625b2713b'	System	23 Sep 2020 02:08:24
User entered 'No (N)'	System	23 Sep 2020 02:08:24

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '2e672584-ab66-42e1-8829-4d9625b2713b'	System	23 Sep 2020 02:08:24
User entered 'No (N)'	System	23 Sep 2020 02:08:24

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '2e672584-ab66-42e1-8829-4d9625b2713b'	System	23 Sep 2020 02:08:24
User entered 'None (1)'	System	23 Sep 2020 02:08:24

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '2e672584-ab66-42e1-8829-4d9625b2713b'	System	23 Sep 2020 02:08:24
User entered '22 Sep 2020 22:08'	System	23 Sep 2020 02:08:24

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 7'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '683d1866-45db-476b-a9a5-8a6f499ce61b'	System	23 Sep 2020 23:28:19
User entered 'None (1)'	System	23 Sep 2020 23:28:19

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '683d1866-45db-476b-a9a5-8a6f499ce61b'	System	23 Sep 2020 23:28:19
User entered 'No (N)'	System	23 Sep 2020 23:28:19

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:27:53', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '683d1866-45db-476b-a9a5-8a6f499ce61b'	System	23 Sep 2020 23:28:19
User entered 'No (N)'	System	23 Sep 2020 23:28:19

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '683d1866-45db-476b-a9a5-8a6f499ce61b'	System	23 Sep 2020 23:28:19
User entered 'None (1)'	System	23 Sep 2020 23:28:19

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:16', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '683d1866-45db-476b-a9a5-8a6f499ce61b'	System	23 Sep 2020 23:28:19
User entered '23 Sep 2020 19:28'	System	23 Sep 2020 23:28:19

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:46', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:53', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:03:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:04:02', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:04:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:04:13', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'None (0)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:04:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered 'No (N)'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T15:04:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dd250f5b-4f48-49b8-a063-b600980ddd22'	System	17 Sep 2020 19:04:47
User entered '17 Sep 2020 15:04'	System	17 Sep 2020 19:04:47

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 14:45'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 17:15'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:18', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:28', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'None (0)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered 'No (N)'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-17T22:38:41', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bf4b8b2b-d0b7-4a56-85e5-c12ea2792cfe'	System	18 Sep 2020 02:38:40
User entered '17 Sep 2020 22:38'	System	18 Sep 2020 02:38:40

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Sep 2020 18:10'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 2'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:24:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:25:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:25:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:25:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:25:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:25:40', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'None (0)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:26:03', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered 'No (N)'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-18T19:26:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0599a1b8-6788-4b0b-ba69-4857b39e9437'	System	18 Sep 2020 23:26:08
User entered '18 Sep 2020 19:26'	System	18 Sep 2020 23:26:08

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 3'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:17:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:17:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:17:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:17:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:17:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:18:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'None (0)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:18:07', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered 'No (N)'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-19T21:18:10', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'be86cec0-2285-47cd-9536-dc941947fc58'	System	20 Sep 2020 01:18:07
User entered '19 Sep 2020 21:18'	System	20 Sep 2020 01:18:07

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 4'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:15', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601' User entered 'None (0)'	System	21 Sep 2020 00:30:46
	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:46', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601'	System	21 Sep 2020 00:30:46
User entered 'No (N)'	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-20T20:30:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baacd69d-bd14-40bd-b67b-b57bd3e99601'	System	21 Sep 2020 00:30:46
User entered '20 Sep 2020 20:30'	System	21 Sep 2020 00:30:46

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 5'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:53', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:08:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'None (0)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:09:03', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered 'No (N)'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-21T21:09:07', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd455e62f-f84b-4faf-b1f4-0323b72911a0'	System	22 Sep 2020 01:09:05
User entered '21 Sep 2020 21:09'	System	22 Sep 2020 01:09:05

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 6'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'No interference with activity (1)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'None (0)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'None (0)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:08:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'None (0)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:09:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'None (0)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:09:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'None (0)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:09:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered 'No (N)'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-22T22:09:15', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8414ecf1-9cfb-4755-b02a-4ba4a4396c99'	System	23 Sep 2020 02:09:13
User entered '22 Sep 2020 22:09'	System	23 Sep 2020 02:09:13

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 7'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:21', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'None (0)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:43', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered 'No (N)'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-09-23T19:28:46', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '71d1c4b3-287e-4e35-b04b-017be5f8f3a8'	System	23 Sep 2020 23:28:49
User entered '23 Sep 2020 19:28'	System	23 Sep 2020 23:28:49

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:29:59

US3602051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:10:54

US3602051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:10:54

US3602051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:10:54

US3602051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:10:54

US3602051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:07:26

US3602051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	14 Oct 2020 18:07:26

US3602051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:12:18

US3602051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:12:18

US3602051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:12:18

US3602051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:12:18

US3602051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:07:51

US3602051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	14 Oct 2020 18:07:51

US3602051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:13:07

US3602051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	30 Oct 2020 17:15:58
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	30 Oct 2020 17:15:58
User entered '8 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:15:58
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Oct 2020 17:15:41
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:15:41
User entered '8 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 17:13:07

US3602051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:13:07

US3602051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:13:07

US3602051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:14

US3602051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	14 Oct 2020 18:08:14

US3602051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:34

US3602051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:34

US3602051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:34

US3602051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'VISIT2'	System	14 Oct 2020 18:08:34

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '13:43'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '90'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'bpm'	System	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'breaths/min'	System	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '105'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '74'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	14 Oct 2020 19:45:15

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '15:55'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '14 Oct 2020 15:55'	System	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Forehead/temporal'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '74'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'bpm'	System	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '15'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'breaths/min'	System	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '108'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '80'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	05 Nov 2020 21:30:28

US3602051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:46:14

US3602051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:46:14

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '15:25'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '14 Oct 2020 15:25'	System	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'ONCE'	System	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 19:35:59

US3602051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:16

US3602051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:16

US3602051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '13:43'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:16

US3602051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 19:47:16

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '13:43'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered empty.	System	14 Oct 2020 19:47:38

US3602051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:44

US3602051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	14 Oct 2020 19:47:44

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:55:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '48a57fe2-2ddb-4774-a63f-1d052cfb2beb'	System	14 Oct 2020 19:55:54
User entered 'Yes (Y)'	System	14 Oct 2020 19:55:54

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:55:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '48a57fe2-2ddb-4774-a63f-1d052cfb2beb'	System	14 Oct 2020 19:55:54
User entered '97.1'	System	14 Oct 2020 19:55:54

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:55:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '48a57fe2-2ddb-4774-a63f-1d052cfb2beb'	System	14 Oct 2020 19:55:54
User entered 'No (N)'	System	14 Oct 2020 19:55:54

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:55:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '48a57fe2-2ddb-4774-a63f-1d052cfb2beb'	System	14 Oct 2020 19:55:54
User entered '14 Oct 2020 15:55'	System	14 Oct 2020 19:55:54

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 15:45'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 18:15'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:07:02', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered 'Yes (Y)'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:07:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered '98.7'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:07:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered 'Yes (Y)'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Comment added 'Correction: Subject was contacted on 21OCT2020 for D36 Safety Call and medication details were determined. Medication has been entered in the ConMed Log eCRF.'	(b) (4), (b) (6)	05 Nov 2020 21:06:32
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 10:31:26
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was not contacted about Adverse event' (Site from System).	(b) (4), (b) (6)	25 Oct 2020 21:45:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Oct 2020 00:09:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:09:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered '1'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:09:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered '0'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:09:35', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8256c522-0037-49f5-a1cd-0e4f08fdbb94'	System	15 Oct 2020 00:09:37
User entered '14 Oct 2020 20:09'	System	15 Oct 2020 00:09:37

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 19:10'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 2'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:50:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3b9eb7bc-687b-4d38-bb95-e17bfdd03853'	System	15 Oct 2020 18:51:22
User entered 'Yes (Y)'	System	15 Oct 2020 18:51:22

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:50:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3b9eb7bc-687b-4d38-bb95-e17bfdd03853'	System	15 Oct 2020 18:51:22
User entered '98.3'	System	15 Oct 2020 18:51:22

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3b9eb7bc-687b-4d38-bb95-e17bfdd03853'	System	15 Oct 2020 18:51:22
User entered 'No (N)'	System	15 Oct 2020 18:51:22

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:20', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3b9eb7bc-687b-4d38-bb95-e17bfdd03853'	System	15 Oct 2020 18:51:22
User entered '15 Oct 2020 14:51'	System	15 Oct 2020 18:51:22

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 3'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:16', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c1c7c859-6897-413e-95dd-69733e01b77a'	System	16 Oct 2020 22:16:53
User entered 'Yes (Y)'	System	16 Oct 2020 22:16:53

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c1c7c859-6897-413e-95dd-69733e01b77a' User entered '98.1'	System	16 Oct 2020 22:16:53
	System	16 Oct 2020 22:16:53

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:35', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c1c7c859-6897-413e-95dd-69733e01b77a'	System	16 Oct 2020 22:16:53
User entered 'No (N)'	System	16 Oct 2020 22:16:53

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c1c7c859-6897-413e-95dd-69733e01b77a'	System	16 Oct 2020 22:16:53
User entered '16 Oct 2020 18:16'	System	16 Oct 2020 22:16:53

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 4'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:04:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '61503c36-cd85-41b7-9126-f52c7ff74ffe'	System	18 Oct 2020 01:05:12
User entered 'Yes (Y)'	System	18 Oct 2020 01:05:12

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '61503c36-cd85-41b7-9126-f52c7ff74ffe'	System	18 Oct 2020 01:05:12
User entered '98.7'	System	18 Oct 2020 01:05:12

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '61503c36-cd85-41b7-9126-f52c7ff74ffe'	System	18 Oct 2020 01:05:12
User entered 'No (N)'	System	18 Oct 2020 01:05:12

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '61503c36-cd85-41b7-9126-f52c7ff74ffe'	System	18 Oct 2020 01:05:12
User entered '17 Oct 2020 21:05'	System	18 Oct 2020 01:05:12

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 5'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6ea614f7-7c64-4f2c-813a-51170a965e61'	System	18 Oct 2020 22:35:27
User entered 'Yes (Y)'	System	18 Oct 2020 22:35:27

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6ea614f7-7c64-4f2c-813a-51170a965e61' User entered '97.1'	System	18 Oct 2020 22:35:27
	System	18 Oct 2020 22:35:27

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6ea614f7-7c64-4f2c-813a-51170a965e61'	System	18 Oct 2020 22:35:27
User entered 'No (N)'	System	18 Oct 2020 22:35:27

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6ea614f7-7c64-4f2c-813a-51170a965e61' User entered '18 Oct 2020 18:35'	System	18 Oct 2020 22:35:27
	System	18 Oct 2020 22:35:27

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 6'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '00541ca4-cb01-464a-9874-3f32b1b171b9'	System	19 Oct 2020 23:28:49
User entered 'Yes (Y)'	System	19 Oct 2020 23:28:49

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:37', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '00541ca4-cb01-464a-9874-3f32b1b171b9' User entered '98.4'	System	19 Oct 2020 23:28:49
	System	19 Oct 2020 23:28:49

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '00541ca4-cb01-464a-9874-3f32b1b171b9'	System	19 Oct 2020 23:28:49
User entered 'No (N)'	System	19 Oct 2020 23:28:49

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '00541ca4-cb01-464a-9874-3f32b1b171b9'	System	19 Oct 2020 23:28:49
User entered '19 Oct 2020 19:28'	System	19 Oct 2020 23:28:49

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 7'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:43:15', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c7037bcb-9ed2-4d5f-9ad5-3de72de750e2'	System	20 Oct 2020 23:44:14
User entered 'Yes (Y)'	System	20 Oct 2020 23:44:14

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:43:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c7037bcb-9ed2-4d5f-9ad5-3de72de750e2'	System	20 Oct 2020 23:44:14
User entered '97.7'	System	20 Oct 2020 23:44:14

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c7037bcb-9ed2-4d5f-9ad5-3de72de750e2'	System	20 Oct 2020 23:44:14
User entered 'No (N)'	System	20 Oct 2020 23:44:14

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:13', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'c7037bcb-9ed2-4d5f-9ad5-3de72de750e2'	System	20 Oct 2020 23:44:14
User entered '20 Oct 2020 19:44'	System	20 Oct 2020 23:44:14

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'efb520ca-9415-40e3-b8fe-cd92df67100a'	System	14 Oct 2020 19:56:17
User entered 'None (1)'	System	14 Oct 2020 19:56:17

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:03', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'efb520ca-9415-40e3-b8fe-cd92df67100a'	System	14 Oct 2020 19:56:17
User entered 'No (N)'	System	14 Oct 2020 19:56:17

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:07', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'efb520ca-9415-40e3-b8fe-cd92df67100a'	System	14 Oct 2020 19:56:17
User entered 'No (N)'	System	14 Oct 2020 19:56:17

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'efb520ca-9415-40e3-b8fe-cd92df67100a'	System	14 Oct 2020 19:56:17
User entered 'None (1)'	System	14 Oct 2020 19:56:17

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:15', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'efb520ca-9415-40e3-b8fe-cd92df67100a'	System	14 Oct 2020 19:56:17
User entered '14 Oct 2020 15:56'	System	14 Oct 2020 19:56:17

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 15:45'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 18:15'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:12:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '953bf105-3096-46dd-9a34-4634492b0c05'	System	15 Oct 2020 00:12:54
User entered 'None (1)'	System	15 Oct 2020 00:12:54

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:12:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '953bf105-3096-46dd-9a34-4634492b0c05'	System	15 Oct 2020 00:12:54
User entered 'No (N)'	System	15 Oct 2020 00:12:54

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:12:41', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '953bf105-3096-46dd-9a34-4634492b0c05'	System	15 Oct 2020 00:12:54
User entered 'No (N)'	System	15 Oct 2020 00:12:54

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:12:48', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '953bf105-3096-46dd-9a34-4634492b0c05'	System	15 Oct 2020 00:12:54
User entered 'None (1)'	System	15 Oct 2020 00:12:54

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:12:52', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '953bf105-3096-46dd-9a34-4634492b0c05'	System	15 Oct 2020 00:12:54
User entered '14 Oct 2020 20:12'	System	15 Oct 2020 00:12:54

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 19:10'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 2'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8d7c254e-b8ea-48fb-b6b3-54a737ed8130'	System	15 Oct 2020 18:52:01
User entered 'None (1)'	System	15 Oct 2020 18:52:01

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8d7c254e-b8ea-48fb-b6b3-54a737ed8130'	System	15 Oct 2020 18:52:01
User entered 'No (N)'	System	15 Oct 2020 18:52:01

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8d7c254e-b8ea-48fb-b6b3-54a737ed8130'	System	15 Oct 2020 18:52:01
User entered 'No (N)'	System	15 Oct 2020 18:52:01

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:51:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8d7c254e-b8ea-48fb-b6b3-54a737ed8130'	System	15 Oct 2020 18:52:01
User entered 'None (1)'	System	15 Oct 2020 18:52:01

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '8d7c254e-b8ea-48fb-b6b3-54a737ed8130'	System	15 Oct 2020 18:52:01
User entered '15 Oct 2020 14:52'	System	15 Oct 2020 18:52:01

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 3'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd26e996b-9a97-4e03-8325-54e027855757'	System	16 Oct 2020 22:17:19
User entered 'None (1)'	System	16 Oct 2020 22:17:19

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:16:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd26e996b-9a97-4e03-8325-54e027855757'	System	16 Oct 2020 22:17:19
User entered 'No (N)'	System	16 Oct 2020 22:17:19

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:03', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd26e996b-9a97-4e03-8325-54e027855757'	System	16 Oct 2020 22:17:19
User entered 'No (N)'	System	16 Oct 2020 22:17:19

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:10', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd26e996b-9a97-4e03-8325-54e027855757'	System	16 Oct 2020 22:17:19
User entered 'None (1)'	System	16 Oct 2020 22:17:19

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd26e996b-9a97-4e03-8325-54e027855757'	System	16 Oct 2020 22:17:19
User entered '16 Oct 2020 18:17'	System	16 Oct 2020 22:17:19

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 4'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:16', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dd543e8-5e39-4acd-8e38-bf855ce73943'	System	18 Oct 2020 01:05:36
User entered 'None (1)'	System	18 Oct 2020 01:05:36

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dd543e8-5e39-4acd-8e38-bf855ce73943'	System	18 Oct 2020 01:05:36
User entered 'No (N)'	System	18 Oct 2020 01:05:36

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dd543e8-5e39-4acd-8e38-bf855ce73943'	System	18 Oct 2020 01:05:36
User entered 'No (N)'	System	18 Oct 2020 01:05:36

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dd543e8-5e39-4acd-8e38-bf855ce73943'	System	18 Oct 2020 01:05:36
User entered 'None (1)'	System	18 Oct 2020 01:05:36

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dd543e8-5e39-4acd-8e38-bf855ce73943'	System	18 Oct 2020 01:05:36
User entered '17 Oct 2020 21:05'	System	18 Oct 2020 01:05:36

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 5'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0d736786-2aef-4963-9f11-e8371dcce64c'	System	18 Oct 2020 22:35:48
User entered 'None (1)'	System	18 Oct 2020 22:35:48

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:35', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0d736786-2aef-4963-9f11-e8371dcce64c'	System	18 Oct 2020 22:35:48
User entered 'No (N)'	System	18 Oct 2020 22:35:48

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0d736786-2aef-4963-9f11-e8371dcce64c'	System	18 Oct 2020 22:35:48
User entered 'No (N)'	System	18 Oct 2020 22:35:48

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0d736786-2aef-4963-9f11-e8371dcce64c'	System	18 Oct 2020 22:35:48
User entered 'None (1)'	System	18 Oct 2020 22:35:48

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '0d736786-2aef-4963-9f11-e8371dcce64c'	System	18 Oct 2020 22:35:48
User entered '18 Oct 2020 18:35'	System	18 Oct 2020 22:35:48

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 6'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:52', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f01c2be8-4c73-440f-82b6-455ee98e7104'	System	19 Oct 2020 23:29:09
User entered 'None (1)'	System	19 Oct 2020 23:29:09

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:56', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f01c2be8-4c73-440f-82b6-455ee98e7104'	System	19 Oct 2020 23:29:09
User entered 'No (N)'	System	19 Oct 2020 23:29:09

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:28:59', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f01c2be8-4c73-440f-82b6-455ee98e7104'	System	19 Oct 2020 23:29:09
User entered 'No (N)'	System	19 Oct 2020 23:29:09

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f01c2be8-4c73-440f-82b6-455ee98e7104'	System	19 Oct 2020 23:29:09
User entered 'None (1)'	System	19 Oct 2020 23:29:09

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f01c2be8-4c73-440f-82b6-455ee98e7104'	System	19 Oct 2020 23:29:09
User entered '19 Oct 2020 19:29'	System	19 Oct 2020 23:29:09

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 7'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:20', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '96595369-104f-4c5b-864d-c5af763d2085'	System	20 Oct 2020 23:44:41
User entered 'None (1)'	System	20 Oct 2020 23:44:41

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '96595369-104f-4c5b-864d-c5af763d2085'	System	20 Oct 2020 23:44:41
User entered 'No (N)'	System	20 Oct 2020 23:44:41

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '96595369-104f-4c5b-864d-c5af763d2085'	System	20 Oct 2020 23:44:41
User entered 'No (N)'	System	20 Oct 2020 23:44:41

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '96595369-104f-4c5b-864d-c5af763d2085'	System	20 Oct 2020 23:44:41
User entered 'None (1)'	System	20 Oct 2020 23:44:41

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '96595369-104f-4c5b-864d-c5af763d2085'	System	20 Oct 2020 23:44:41
User entered '20 Oct 2020 19:44'	System	20 Oct 2020 23:44:41

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:40', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'None (0)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered 'No (N)'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T15:56:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f639f95-fcb1-44ce-b4b2-e7b914ed7dd9'	System	14 Oct 2020 19:56:55
User entered '14 Oct 2020 15:56'	System	14 Oct 2020 19:56:55

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 15:45'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 18:15'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:13:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'No interference with activity (1)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'No interference with activity (1)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:10', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'None (0)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'None (0)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:18', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'None (0)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:20', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'None (0)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered 'No (N)'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-14T20:14:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3f1bb9a0-a0f4-4bea-80cd-ec5befda2fe6'	System	15 Oct 2020 00:14:36
User entered '14 Oct 2020 20:14'	System	15 Oct 2020 00:14:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '14 Oct 2020 19:10'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 2'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:22', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:30', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'None (0)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:40', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered 'No (N)'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-15T14:52:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd083496e-96e0-4736-9d5f-c6017e3e3d52'	System	15 Oct 2020 18:52:46
User entered '15 Oct 2020 14:52'	System	15 Oct 2020 18:52:46

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 3'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:48', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'None (0)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:56', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered 'No (N)'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-16T18:17:59', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b3bb6d52-67bf-40da-9dff-e0451e5a6307'	System	16 Oct 2020 22:18:03
User entered '16 Oct 2020 18:17'	System	16 Oct 2020 22:18:03

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 4'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f'	System	18 Oct 2020 01:06:14
User entered 'None (0)'	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:48', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f' User entered 'None (0)'	System	18 Oct 2020 01:06:14
	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:52', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f' User entered 'None (0)'	System	18 Oct 2020 01:06:14
	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:05:56', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f'	System	18 Oct 2020 01:06:14
User entered 'None (0)'	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:06:05', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f'	System	18 Oct 2020 01:06:14
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:06:08', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f' User entered 'None (0)'	System	18 Oct 2020 01:06:14
	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:06:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f'	System	18 Oct 2020 01:06:14
User entered 'No (N)'	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-17T21:06:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '08d6a4f9-f148-4b0e-ab7c-ad3807c1ac6f' User entered '17 Oct 2020 21:06'	System	18 Oct 2020 01:06:14
	System	18 Oct 2020 01:06:14

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 5'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:35:52', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'None (0)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'No interference with activity (1)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:07', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'No interference with activity (1)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:18', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'No interference with activity (1)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:22', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'None (0)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'None (0)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:30', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered 'No (N)'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-18T18:36:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'cfc626bf-c390-4fe1-a099-c3db6a0447c2'	System	18 Oct 2020 22:36:36
User entered '18 Oct 2020 18:36'	System	18 Oct 2020 22:36:36

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 6'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:13', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'None (0)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'No interference with activity (1)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:28', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'None (0)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a' User entered 'None (0)'	System	19 Oct 2020 23:29:44
	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:33', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'None (0)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'None (0)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:40', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered 'No (N)'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-19T19:29:43', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '675e3c61-c583-46db-81c5-58979266f33a'	System	19 Oct 2020 23:29:44
User entered '19 Oct 2020 19:29'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	14 Oct 2020 19:35:59
User entered 'Day 7'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered 'None (0)'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered 'No interference with activity (1)'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:54', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f' User entered 'None (0)'	System	20 Oct 2020 23:45:16
	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:44:57', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f' User entered 'None (0)'	System	20 Oct 2020 23:45:16
	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:45:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered 'None (0)'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:45:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered 'None (0)'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:45:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered 'No (N)'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-20T19:45:12', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '028f36dd-dd20-4532-bfe9-d2b163cccf8f'	System	20 Oct 2020 23:45:16
User entered '20 Oct 2020 19:45'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:35:59

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	19 Oct 2020 23:29:44
User entered 'Day 8'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-21T18:50:24', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dc0305f-2df7-45bc-adae-4d3d83798dac'	System	21 Oct 2020 22:50:31
User entered 'No interference with activity (1)'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-21T18:50:28', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '9dc0305f-2df7-45bc-adae-4d3d83798dac'	System	21 Oct 2020 22:50:31
User entered '21 Oct 2020 18:50'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	20 Oct 2020 23:45:16
User entered 'Day 9'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-22T18:24:20', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '26235d92-38cf-4562-89f7-9fb4a5e755b3'	System	22 Oct 2020 22:24:27
User entered 'No interference with activity (1)'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-22T18:24:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '26235d92-38cf-4562-89f7-9fb4a5e755b3'	System	22 Oct 2020 22:24:27
User entered '22 Oct 2020 18:24'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	21 Oct 2020 22:50:31
User entered 'Day 10'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-23T22:07:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '018bbe56-e611-4ce9-8856-d8e3cd241a44'	System	24 Oct 2020 02:07:18
User entered 'No interference with activity (1)'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-23T22:07:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '018bbe56-e611-4ce9-8856-d8e3cd241a44'	System	24 Oct 2020 02:07:18
User entered '23 Oct 2020 22:07'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	22 Oct 2020 22:24:27
User entered 'Day 11'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-24T18:41:13', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '401e22d9-242b-4fad-b5e9-071cf06efbe1'	System	24 Oct 2020 22:41:17
User entered 'No interference with activity (1)'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-24T18:41:17', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '401e22d9-242b-4fad-b5e9-071cf06efbe1'	System	24 Oct 2020 22:41:17
User entered '24 Oct 2020 18:41'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	24 Oct 2020 02:07:18
User entered 'Day 12'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-25T20:24:37', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3ae985ef-d394-41be-a636-57fbb19a5b4d'	System	26 Oct 2020 00:24:40
User entered 'No interference with activity (1)'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-25T20:24:40', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3ae985ef-d394-41be-a636-57fbb19a5b4d'	System	26 Oct 2020 00:24:40
User entered '25 Oct 2020 20:24'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	24 Oct 2020 22:41:17
User entered 'Day 13'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-26T20:01:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f4181367-7f1a-4132-9652-c597f312aa2d'	System	27 Oct 2020 00:01:34
User entered 'No interference with activity (1)'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-26T20:01:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f4181367-7f1a-4132-9652-c597f312aa2d'	System	27 Oct 2020 00:01:34
User entered '26 Oct 2020 20:01'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	26 Oct 2020 00:24:40
User entered 'Day 14'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	27 Oct 2020 00:01:34
User entered 'Day 15'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	19 Oct 2020 23:29:44
User entered 'Day 8'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-21T18:50:35', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '5434354e-a1ac-4ed1-ac07-23151793709c'	System	21 Oct 2020 22:50:44
User entered 'No (N)'	System	21 Oct 2020 22:50:44

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-21T18:50:38', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '5434354e-a1ac-4ed1-ac07-23151793709c'	System	21 Oct 2020 22:50:44
User entered '21 Oct 2020 18:50'	System	21 Oct 2020 22:50:44

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 23:29:44

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	20 Oct 2020 23:45:16
User entered 'Day 9'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-22T18:24:29', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '751ed714-9acc-46a0-af38-cb63d93e71c0'	System	22 Oct 2020 22:24:37
User entered 'No (N)'	System	22 Oct 2020 22:24:37

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-22T18:24:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '751ed714-9acc-46a0-af38-cb63d93e71c0'	System	22 Oct 2020 22:24:37
User entered '22 Oct 2020 18:24'	System	22 Oct 2020 22:24:37

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 23:45:16

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	21 Oct 2020 22:50:31
User entered 'Day 10'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-23T22:07:21', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '742fdac0-befc-4dd8-869c-ca7a9dca11de'	System	24 Oct 2020 02:07:24
User entered 'No (N)'	System	24 Oct 2020 02:07:24

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-23T22:07:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '742fdac0-befc-4dd8-869c-ca7a9dca11de'	System	24 Oct 2020 02:07:24
User entered '23 Oct 2020 22:07'	System	24 Oct 2020 02:07:24

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:50:31

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	22 Oct 2020 22:24:27
User entered 'Day 11'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-24T18:41:21', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd42d53c8-5c22-4e22-b882-91ff563ecc15'	System	24 Oct 2020 22:41:25
User entered 'No (N)'	System	24 Oct 2020 22:41:25

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-24T18:41:23', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd42d53c8-5c22-4e22-b882-91ff563ecc15'	System	24 Oct 2020 22:41:25
User entered '24 Oct 2020 18:41'	System	24 Oct 2020 22:41:25

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:24:27

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	24 Oct 2020 02:07:18
User entered 'Day 12'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-25T20:24:44', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '5cd17d70-0deb-4839-abf6-f7c33b1895f9'	System	26 Oct 2020 00:24:47
User entered 'No (N)'	System	26 Oct 2020 00:24:47

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-25T20:24:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '5cd17d70-0deb-4839-abf6-f7c33b1895f9'	System	26 Oct 2020 00:24:47
User entered '25 Oct 2020 20:24'	System	26 Oct 2020 00:24:47

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 02:07:18

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	24 Oct 2020 22:41:17
User entered 'Day 13'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-26T20:01:32', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'eff9dc24-f17c-4b63-b1ac-3d5db2ac5876'	System	27 Oct 2020 00:01:40
User entered 'No (N)'	System	27 Oct 2020 00:01:40

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-10-26T20:01:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'eff9dc24-f17c-4b63-b1ac-3d5db2ac5876'	System	27 Oct 2020 00:01:40
User entered '26 Oct 2020 20:01'	System	27 Oct 2020 00:01:40

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:41:17

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	26 Oct 2020 00:24:40
User entered 'Day 14'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 00:24:40

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	27 Oct 2020 00:01:34
User entered 'Day 15'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

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 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 00:01:34

US3602051

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:10:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 00:01:34

US3602051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Oct 2020 21:46:54

US3602051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	25 Oct 2020 21:46:54

US3602051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Oct 2020 21:46:54

US3602051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Oct 2020 21:46:54

US3602051

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:17:04

US3602051

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	30 Oct 2020 17:17:04

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Nov 2020 20:47:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:47:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:47:36
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:19:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:19:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 17:18:24

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
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) (b) (4), (b) (6)	18 Nov 2020 04:07:18
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.'	(b) (4), (b) (6)	17 Nov 2020 20:49:24
answered with 'Subject contacted site on 27OCT2020 for D43 Safety Call as they were scheduled for AVR surgery (see concomitant procedures log eCRF) on 28OCT2020 and would not be available for call.' (Site from System).		
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	17 Nov 2020 20:47:36
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:47:36
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).	System	30 Oct 2020 17:19:33
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.'	System	30 Oct 2020 17:19:33
answered by data change (Site from System).		
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:19:33
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	30 Oct 2020 17:18:24

PRODUCTION RELEASE (v12.003
EAB) (1725)

1339 of 2984

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 17:18:24

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 17:19:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 17:18:24

US3602051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:19:33
User entered 'Subject called 24 hour vaccine hotline ie this writer at 2000 27-Oct-2020 to inform study team that tomorrow he is scheduled for surgical repair at Hackensack Meridian Health for aortic stenosis (previouslyt documented condition, present before 1rstr sutdy injection). Subject is asymptomatic with no discomforts or concerns at time of call or since previous contact. He is scheduled for day 43 safety call 28-Oct-2020. This writer recorded safety call at time of contact as subject states that he anticipates being unavailable due to scheduled surgery 28-OCT-2020: see below;' (non-conformant).	(b) (4), (b) (6)	30 Oct 2020 17:18:24

US3602051

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:18:46

US3602051

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	30 Oct 2020 17:18:46

US3602051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:35:04

US3602051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:35:04

US3602051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:35:04

US3602051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:35:04

US3602051

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:35:13

US3602051

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	06 Nov 2020 16:35:13

US3602051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:29:55

US3602051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:29:55

US3602051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:29:55

US3602051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'VISIT3'	System	11 Nov 2020 19:29:55

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '12:28'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '11 Nov 2020 12:28'	System	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
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)	12 Nov 2020 03:15:45
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.'	(b) (4), (b) (6)	11 Nov 2020 19:31:40
answered with 'NCS' (Site from System).		
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	11 Nov 2020 19:31:22
User entered '96.2' F	(b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'FOREHEAD/TEMPORAL' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 19:31:34
User entered 'Forehead/termporal'	(b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '79'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'bpm'	System	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'breaths/min'	System	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '110'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '78'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered 'mmHg'	System	11 Nov 2020 19:31:22

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33

US3602051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33

US3602051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:10

US3602051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:10

US3602051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:37

US3602051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:37

US3602051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered '12:28'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:37

US3602051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '11 Nov 2020 12:28'	System	11 Nov 2020 19:32:37

US3602051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	16 Feb 2021 19:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:32:47

US3602051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	11 Nov 2020 19:32:47

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered 'Day 64'	System	17 Sep 2020 18:29:59

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-11-17T09:38:16', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e1464d7f-592a-4507-adb9-9be3a9e68031'	System	17 Nov 2020 14:38:38
User entered 'No (N)'	System	17 Nov 2020 14:38:38

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-11-17T09:38:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e1464d7f-592a-4507-adb9-9be3a9e68031'	System	17 Nov 2020 14:38:38
User entered 'No (N)'	System	17 Nov 2020 14:38:38

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-11-17T09:38:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e1464d7f-592a-4507-adb9-9be3a9e68031'	System	17 Nov 2020 14:38:38
User entered '17 Nov 2020 09:38:34'	System	17 Nov 2020 14:38:38

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 18:29:59

US3602051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:35:33
Data entry locked.	System	17 Sep 2020 18:29:59
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 18:29:59

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-11-22T19:47:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '94465bce-ac88-4f9a-98cc-fb7d074a5082'	System	23 Nov 2020 00:47:29
User entered 'No (N)'	System	23 Nov 2020 00:47:29

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2020-11-22T19:47:26', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '94465bce-ac88-4f9a-98cc-fb7d074a5082'	System	23 Nov 2020 00:47:29
User entered 'No (N)'	System	23 Nov 2020 00:47:29

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-11-22T19:47:28', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '94465bce-ac88-4f9a-98cc-fb7d074a5082'	System	23 Nov 2020 00:47:29
User entered '22 Nov 2020 19:47:28'	System	23 Nov 2020 00:47:29

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-11-28T10:00:56', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4ceb0a9e-3264-4bda-9937-b186b58432fd'	System	28 Nov 2020 15:01:12
User entered 'No (N)'	System	28 Nov 2020 15:01:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-11-28T10:01:07', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4ceb0a9e-3264-4bda-9937-b186b58432fd'	System	28 Nov 2020 15:01:12
User entered 'No (N)'	System	28 Nov 2020 15:01:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-11-28T10:01:10', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4ceb0a9e-3264-4bda-9937-b186b58432fd' User entered '28 Nov 2020 10:01:10'	System	28 Nov 2020 15:01:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-05T13:00:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3d80ac77-a3c8-4d89-9388-9c668188c1cf'	System	05 Dec 2020 18:00:46
User entered 'No (N)'	System	05 Dec 2020 18:00:46

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-05T13:00:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3d80ac77-a3c8-4d89-9388-9c668188c1cf'	System	05 Dec 2020 18:00:46
User entered 'No (N)'	System	05 Dec 2020 18:00:46

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-12-05T13:00:45', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '3d80ac77-a3c8-4d89-9388-9c668188c1cf' User entered '05 Dec 2020 13:00:45'	System	05 Dec 2020 18:00:46
	System	05 Dec 2020 18:00:46

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-12T00:07:14', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f17520f1-556b-43b5-b22c-a15b29c8e0b4'	System	12 Dec 2020 05:07:27
User entered 'No (N)'	System	12 Dec 2020 05:07:27

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2020-12-12T00:07:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f17520f1-556b-43b5-b22c-a15b29c8e0b4'	System	12 Dec 2020 05:07:27
User entered 'No (N)'	System	12 Dec 2020 05:07:27

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-12-12T00:07:22', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f17520f1-556b-43b5-b22c-a15b29c8e0b4' User entered '12 Dec 2020 00:07:22'	System	12 Dec 2020 05:07:27
	System	12 Dec 2020 05:07:27

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-19T00:27:56', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bc8670a0-da7d-4027-8853-45ff7395fd8f'	System	19 Dec 2020 05:28:07
User entered 'No (N)'	System	19 Dec 2020 05:28:07

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2020-12-19T00:28:04', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bc8670a0-da7d-4027-8853-45ff7395fd8f'	System	19 Dec 2020 05:28:07
User entered 'No (N)'	System	19 Dec 2020 05:28:07

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-12-19T00:28:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'bc8670a0-da7d-4027-8853-45ff7395fd8f' User entered '19 Dec 2020 00:28:06'	System	19 Dec 2020 05:28:07
	System	19 Dec 2020 05:28:07

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-26T21:52:47', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b9c076f9-8c84-47a1-bc57-1445bb739ff5'	System	27 Dec 2020 02:53:02
User entered 'No (N)'	System	27 Dec 2020 02:53:02

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2020-12-26T21:52:58', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b9c076f9-8c84-47a1-bc57-1445bb739ff5'	System	27 Dec 2020 02:53:02
User entered 'No (N)'	System	27 Dec 2020 02:53:02

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2020-12-26T21:53:01', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'b9c076f9-8c84-47a1-bc57-1445bb739ff5' User entered '26 Dec 2020 21:53:01'	System	27 Dec 2020 02:53:02
	System	27 Dec 2020 02:53:02

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-02T01:29:11', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4fcd69ee-6b9a-4035-9ea5-2ebce8bbbf5'	System	02 Jan 2021 06:29:22
User entered 'No (N)'	System	02 Jan 2021 06:29:22

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-02T01:29:19', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4fcd69ee-6b9a-4035-9ea5-2ebce8bbbfb5'	System	02 Jan 2021 06:29:22
User entered 'No (N)'	System	02 Jan 2021 06:29:22

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-01-02T01:29:21', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4fcd69ee-6b9a-4035-9ea5-2ebce8bbbfb5'	System	02 Jan 2021 06:29:22
User entered '02 Jan 2021 01:29:21'	System	02 Jan 2021 06:29:22

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-09T01:58:31', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '51f9732c-3709-4d11-9e04-b7edeebfd42f'	System	09 Jan 2021 06:59:41
User entered 'No (N)'	System	09 Jan 2021 06:59:41

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-09T01:59:37', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '51f9732c-3709-4d11-9e04-b7edeebfd42f'	System	09 Jan 2021 06:59:41
User entered 'No (N)'	System	09 Jan 2021 06:59:41

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-01-09T01:59:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '51f9732c-3709-4d11-9e04-b7edeebfd42f' User entered '09 Jan 2021 01:59:39'	System	09 Jan 2021 06:59:41
	System	09 Jan 2021 06:59:41

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-16T21:50:02', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'fccf56ca-3787-4848-bebf-32b0eeb51880'	System	17 Jan 2021 02:50:42
User entered 'No (N)'	System	17 Jan 2021 02:50:42

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-16T21:50:34', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'fccf56ca-3787-4848-bebf-32b0eeb51880'	System	17 Jan 2021 02:50:42
User entered 'No (N)'	System	17 Jan 2021 02:50:42

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-01-16T21:50:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'fccf56ca-3787-4848-bebf-32b0eeb51880'	System	17 Jan 2021 02:50:42
User entered '16 Jan 2021 21:50:39'	System	17 Jan 2021 02:50:42

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-23T00:01:49', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4c37e211-7262-4e1a-86e7-73bd5a01bc50'	System	23 Jan 2021 05:02:57
User entered 'No (N)'	System	23 Jan 2021 05:02:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-23T00:01:59', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4c37e211-7262-4e1a-86e7-73bd5a01bc50'	System	23 Jan 2021 05:02:57
User entered 'No (N)'	System	23 Jan 2021 05:02:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-01-23T00:02:18', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '4c37e211-7262-4e1a-86e7-73bd5a01bc50'	System	23 Jan 2021 05:02:57
User entered '23 Jan 2021 00:02:18'	System	23 Jan 2021 05:02:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-30T12:38:41', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '012666d2-bb84-43f1-b26e-6cf029ea5efa'	System	30 Jan 2021 17:39:00
User entered 'No (N)'	System	30 Jan 2021 17:39:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-01-30T12:38:51', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '012666d2-bb84-43f1-b26e-6cf029ea5efa'	System	30 Jan 2021 17:39:00
User entered 'No (N)'	System	30 Jan 2021 17:39:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-01-30T12:38:57', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '012666d2-bb84-43f1-b26e-6cf029ea5efa' User entered '30 Jan 2021 12:38:57'	System	30 Jan 2021 17:39:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-06T01:11:25', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'feccc156-7cdd-46e1-92a8-f6fd9b2c21d8'	System	06 Feb 2021 06:11:52
User entered 'No (N)'	System	06 Feb 2021 06:11:52

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-06T01:11:42', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'feccc156-7cdd-46e1-92a8-f6fd9b2c21d8'	System	06 Feb 2021 06:11:52
User entered 'No (N)'	System	06 Feb 2021 06:11:52

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-02-06T01:11:46', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'feccc156-7cdd-46e1-92a8-f6fd9b2c21d8'	System	06 Feb 2021 06:11:52
User entered '06 Feb 2021 01:11:46'	System	06 Feb 2021 06:11:52

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-13T00:31:27', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd520a78c-fd45-484e-aed2-b2f68edd5949'	System	13 Feb 2021 05:37:21
User entered 'No (N)'	System	13 Feb 2021 05:37:21

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-13T00:31:36', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd520a78c-fd45-484e-aed2-b2f68edd5949'	System	13 Feb 2021 05:37:21
User entered 'No (N)'	System	13 Feb 2021 05:37:21

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-02-13T00:31:39', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'd520a78c-fd45-484e-aed2-b2f68edd5949'	System	13 Feb 2021 05:37:21
User entered '13 Feb 2021 00:31:39'	System	13 Feb 2021 05:37:21

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-20T01:38:55', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f3754987-af1a-4344-82c0-d49cf2a5d356'	System	20 Feb 2021 06:39:12
User entered 'No (N)'	System	20 Feb 2021 06:39:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-02-20T01:39:06', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f3754987-af1a-4344-82c0-d49cf2a5d356'	System	20 Feb 2021 06:39:12
User entered 'No (N)'	System	20 Feb 2021 06:39:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-02-20T01:39:09', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f3754987-af1a-4344-82c0-d49cf2a5d356'	System	20 Feb 2021 06:39:12
User entered '20 Feb 2021 01:39:09'	System	20 Feb 2021 06:39:12

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-01T00:25:17-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '46058903-58c8-47f8-9cf3-30d51982199d'	System	01 Mar 2021 05:25:40
User entered 'No (N)'	System	01 Mar 2021 05:25:40

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-03-01T00:25:32-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '46058903-58c8-47f8-9cf3-30d51982199d'	System	01 Mar 2021 05:25:40
User entered 'No (N)'	System	01 Mar 2021 05:25:40

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-01T00:25:35-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '46058903-58c8-47f8-9cf3-30d51982199d'	System	01 Mar 2021 05:25:40
User entered '01 Mar 2021 00:25:35'	System	01 Mar 2021 05:25:40

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-06T00:35:06-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '213d4196-9950-4517-96e9-8cafa625b4b2'	System	06 Mar 2021 05:36:58
User entered 'No (N)'	System	06 Mar 2021 05:36:58

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-03-06T00:35:13-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '213d4196-9950-4517-96e9-8cafa625b4b2'	System	06 Mar 2021 05:36:58
User entered 'No (N)'	System	06 Mar 2021 05:36:58

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-06T00:35:15-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '213d4196-9950-4517-96e9-8cafa625b4b2'	System	06 Mar 2021 05:36:58
User entered '06 Mar 2021 00:35:15'	System	06 Mar 2021 05:36:58

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-13T00:21:50-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'df4c2f21-6014-40e2-aeb8-b9e0205f278d'	System	13 Mar 2021 05:22:05
User entered 'No (N)'	System	13 Mar 2021 05:22:05

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-03-13T00:21:59-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'df4c2f21-6014-40e2-aeb8-b9e0205f278d'	System	13 Mar 2021 05:22:05
User entered 'No (N)'	System	13 Mar 2021 05:22:05

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-13T00:22:02-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'df4c2f21-6014-40e2-aeb8-b9e0205f278d'	System	13 Mar 2021 05:22:05
User entered '13 Mar 2021 00:22:02'	System	13 Mar 2021 05:22:05

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-20T12:45:43-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dc555567-db52-40b8-919f-59be7f9e6fa0'	System	20 Mar 2021 16:45:57
User entered 'No (N)'	System	20 Mar 2021 16:45:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-03-20T12:45:52-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dc555567-db52-40b8-919f-59be7f9e6fa0'	System	20 Mar 2021 16:45:57
User entered 'No (N)'	System	20 Mar 2021 16:45:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-20T12:45:55-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'dc555567-db52-40b8-919f-59be7f9e6fa0'	System	20 Mar 2021 16:45:57
User entered '20 Mar 2021 12:45:55'	System	20 Mar 2021 16:45:57

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-27T14:53:46-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6e18971d-62e4-4914-90fb-8a6c220bd8e9'	System	27 Mar 2021 18:53:54
User entered 'No (N)'	System	27 Mar 2021 18:53:54

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-03-27T14:53:50-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6e18971d-62e4-4914-90fb-8a6c220bd8e9'	System	27 Mar 2021 18:53:54
User entered 'No (N)'	System	27 Mar 2021 18:53:54

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-27T14:53:53-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '6e18971d-62e4-4914-90fb-8a6c220bd8e9' User entered '27 Mar 2021 14:53:53'	System	27 Mar 2021 18:53:54
	System	27 Mar 2021 18:53:54

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-04-03T14:26:12-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '242151d3-b973-4593-9184-660cc10fa8e8'	System	03 Apr 2021 18:26:39
User entered 'No (N)'	System	03 Apr 2021 18:26:39

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-04-03T14:26:30-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '242151d3-b973-4593-9184-660cc10fa8e8'	System	03 Apr 2021 18:26:39
User entered 'No (N)'	System	03 Apr 2021 18:26:39

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-04-03T14:26:32-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: '242151d3-b973-4593-9184-660cc10fa8e8'	System	03 Apr 2021 18:26:39
User entered '03 Apr 2021 14:26:32'	System	03 Apr 2021 18:26:39

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-04-10T19:49:08-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baa55187-69ef-40d3-9b0c-c15a71f06980'	System	10 Apr 2021 23:49:18
User entered 'No (N)'	System	10 Apr 2021 23:49:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-04-10T19:49:13-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baa55187-69ef-40d3-9b0c-c15a71f06980'	System	10 Apr 2021 23:49:18
User entered 'No (N)'	System	10 Apr 2021 23:49:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-04-10T19:49:15-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'baa55187-69ef-40d3-9b0c-c15a71f06980'	System	10 Apr 2021 23:49:18
User entered '10 Apr 2021 19:49:15'	System	10 Apr 2021 23:49:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-04-18T14:14:47-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a659d5e5-a276-4ff1-b81b-58fa3ff3751d' User entered 'No (N)'	System	18 Apr 2021 18:15:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-04-18T14:14:53-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a659d5e5-a276-4ff1-b81b-58fa3ff3751d'	System	18 Apr 2021 18:15:00
User entered 'No (N)'	System	18 Apr 2021 18:15:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-04-18T14:14:56-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'a659d5e5-a276-4ff1-b81b-58fa3ff3751d' User entered '18 Apr 2021 14:14:56'	System	18 Apr 2021 18:15:00

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-04-24T00:02:28-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f2c07f5f-c67e-4784-9085-dedd118bd218'	System	24 Apr 2021 04:07:18
User entered 'No (N)'	System	24 Apr 2021 04:07:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

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 (ab7d8f51c743e019)', Time: '2021-04-24T00:02:32-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f2c07f5f-c67e-4784-9085-dedd118bd218'	System	24 Apr 2021 04:07:18
User entered 'No (N)'	System	24 Apr 2021 04:07:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-04-24T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'f2c07f5f-c67e-4784-9085-dedd118bd218' User entered '24 Apr 2021 00:02:34'	System	24 Apr 2021 04:07:18
	System	24 Apr 2021 04:07:18

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-05-01T01:14:54-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e2f03206-f137-4cb0-8b68-610fb62a8102'	System	01 May 2021 05:25:36
User entered 'No (N)'	System	01 May 2021 05:25:36

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[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 (ab7d8f51c743e019)', Time: '2021-05-01T01:14:58-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e2f03206-f137-4cb0-8b68-610fb62a8102'	System	01 May 2021 05:25:36
User entered 'No (N)'	System	01 May 2021 05:25:36

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-05-01T01:15:14-04:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'e2f03206-f137-4cb0-8b68-610fb62a8102'	System	01 May 2021 05:25:36
User entered '01 May 2021 01:15:14'	System	01 May 2021 05:25:36

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:14:43

US3602051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:43
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:14:43

US3602051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:10:45

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)	25 Apr 2021 15:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-01T00:26:00-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ae283f50-c2c0-4f38-bf5f-2107956e264a'	System	01 Mar 2021 05:26:10
User entered 'No (N)'	System	01 Mar 2021 05:26:10

US3602051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:10:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ab7d8f51c743e019)', Time: '2021-03-01T00:26:06-05:00', User OID: 'PatientReportedOutcome (US3602051)', ODM File OID: 'ae283f50-c2c0-4f38-bf5f-2107956e264a'	System	01 Mar 2021 05:26:10
User entered '01 Mar 2021 00:26:06'	System	01 Mar 2021 05:26:10

US3602051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:07

US3602051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:07

US3602051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:07

US3602051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:07

US3602051

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:15

US3602051

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:32:33
User entered '1'	System	10 Dec 2020 16:28:15

US3602051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:12:48

US3602051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:12:48

US3602051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:12:48

US3602051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:12:48

US3602051

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:12:54

US3602051

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '1'	System	13 Jan 2021 18:12:54

US3602051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:19

US3602051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:19

US3602051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:19

US3602051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:19

US3602051

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:04

US3602051

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '1'	System	15 Feb 2021 19:59:04

US3602051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:39:43

US3602051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:39:43

US3602051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:39:43

US3602051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:39:43

US3602051

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:03

US3602051

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '1'	System	17 Mar 2021 15:42:03

US3602051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:33

US3602051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:33

US3602051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:33

US3602051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered 'VISIT4'	System	30 Mar 2021 18:58:33

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '13:24'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '30 Mar 2021 13:24'	System	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
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)	31 Mar 2021 08:27:05
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.'	(b) (4), (b) (6)	30 Mar 2021 18:59:41
answered with 'NCS' (Site from System).		
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	30 Mar 2021 18:59:34
User entered '96.7' F	(b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '86'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered 'bpm'	System	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '18'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered 'breaths/min'	System	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '103'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered 'mmHg'	System	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '83'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered 'mmHg'	System	30 Mar 2021 18:59:34

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27

US3602051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27

US3602051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:40:09

US3602051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:40:09

US3602051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:00:00

US3602051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:00:00

US3602051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '13:30'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:00:00

US3602051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '30 Mar 2021 13:30'	System	30 Mar 2021 19:00:00

US3602051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:00:05

US3602051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:10:27
User entered '1'	System	30 Mar 2021 19:00:05

US3602051

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:33

US3602051

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:33

US3602051

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:33

US3602051

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 19:31:33

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[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 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:41

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:41

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:34:53
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:34:53
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	18 Jan 2021 19:31:50

US3602051

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	18 Jan 2021 19:31:50

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered empty.	System	18 Jan 2021 19:35:20
DataPoint set to visible.	System	18 Jan 2021 19:31:50

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered empty.	System	18 Jan 2021 19:35:20
DataPoint set to visible.	System	18 Jan 2021 19:31:50

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '13:10'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '18 Jan 2021 13:10'	System	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '100'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'bpm'	System	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'breaths/min'	System	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '128'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '89'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:20

US3602051

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered empty.	System	18 Jan 2021 19:35:20
DataPoint set to visible.	System	18 Jan 2021 19:31:50

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '15:24'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '18 Jan 2021 15:24'	System	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '88'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'bpm'	System	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'breaths/min'	System	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '117'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '87'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:58

US3602051

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	18 Jan 2021 22:28:58

US3602051

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:37

US3602051

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:35:37

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mRNA-1273'	System	18 Jan 2021 20:06:46
DataPoint set to visible.	System	18 Jan 2021 19:31:50

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '14:54'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '18 Jan 2021 14:54'	System	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'ONCE'	System	18 Jan 2021 20:06:46

US3602051

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 20:06:46

US3602051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:15

US3602051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:15

US3602051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '13:30'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:15

US3602051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '18 Jan 2021 13:30'	System	18 Jan 2021 19:32:15

US3602051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:28

US3602051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:28

US3602051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '13:25'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:32:28

US3602051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '18 Jan 2021 13:25'	System	18 Jan 2021 19:32:28

US3602051

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

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:32:42

US3602051

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

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	18 Jan 2021 22:32:42

US3602051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:32

US3602051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:32

US3602051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:32

US3602051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:32

US3602051

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:36

US3602051

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	27 Jan 2021 15:39:36

US3602051

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	27 Jan 2021 15:39:36
DataPoint set to visible.	System	27 Jan 2021 15:39:36

US3602051

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:04

US3602051

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:04

US3602051

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[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 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:04

US3602051

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'OLD29'	System	17 Feb 2021 18:04:04

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '12:15'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '17 Feb 2021 12:15'	System	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '83'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'bpm'	System	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'breaths/min'	System	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '134'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '66'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	17 Feb 2021 18:58:38

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '14:10'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '17 Feb 2021 14:10'	System	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '68'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'bpm'	System	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'breaths/min'	System	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '115'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '79'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mmHg'	System	17 Feb 2021 19:32:27

US3602051

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:55

US3602051

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:58:55

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'mRNA-1273'	System	17 Feb 2021 18:59:30
DataPoint set to visible.	System	27 Jan 2021 15:39:36

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '13:35'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '17 Feb 2021 13:35'	System	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'ONCE'	System	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 18:59:30

US3602051

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:32:34

US3602051

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	17 Feb 2021 19:32:34

US3602051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 01:58:21

US3602051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 01:58:21

US3602051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 01:58:21

US3602051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 01:58:21

US3602051

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 01:57:42

US3602051

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:51
User entered '1'	System	02 Mar 2021 01:57:42

US3602051

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:30

US3602051

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:30

US3602051

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:56:30

US3602051

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:45

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:56:30

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '13:24'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:24'	System	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
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)	31 Mar 2021 08:26:47
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)	30 Mar 2021 18:57:43
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	30 Mar 2021 18:57:35
User entered '96.7' F	(b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '86'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '18'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '103'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '83'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:57:35

US3602051

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:59

US3602051

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:57:59

US3602051

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:14

US3602051

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:14

US3602051

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User entered '13:30'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:58:14

US3602051

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:30'	System	30 Mar 2021 18:58:14

US3602051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:10:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 14Oct2020; end date: Day 13 - 26Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 02:54:38
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 14Oct2020; end date: Day 13 - 26Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'As per D36 Safety Call notes on 21-Oct-2020 and D43 Safety Call notes on 27-Oct-2020, subject did not report solicited AR "fatigue."' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:19:17
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 14Oct2020; end date: Day 13 - 26Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:27:21
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:56:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:31:25

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 11:31:09
Query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'SAR does not meet AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:38:05
User opened query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:53:33
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)	05 Nov 2020 21:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 21:34:17
Data point term sent to Coder	System	05 Nov 2020 21:33:19
User entered 'Headache'	(b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '18:00'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User entered '14 Oct 2020 18:00'	System	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '21:00'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User entered '14 Oct 2020 21:00'	System	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User entered '0'	System	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29
User entered '0'	System	05 Nov 2020 21:32:54

US3602051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:29

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:39:41
User entered 'USA-US079-2020-mRNA-1273-P301000004'	System	06 Nov 2020 19:38:38
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 19:38:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:21:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:21:22
Data point term sent to Coder	System	06 Nov 2020 16:56:37
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 16:55:38
User entered 'Worsening of Aortic stenosis' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:55:38
Data point term sent to Coder	System	06 Nov 2020 16:55:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
Data point term sent to Coder	System	06 Nov 2020 14:12:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Aortic valve replacement, LLT: Aortic valve replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:42:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:42:25
Data point term sent to Coder	System	05 Nov 2020 21:41:44
User entered 'Aortic Valve Replacement'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Nov 2020 21:43:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:43:08
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	05 Nov 2020 21:41:40
User entered '13:03'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered empty.	System	05 Nov 2020 21:43:08
User entered '28 Oct 2020 13:03'	System	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
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	05 Nov 2020 21:43:08
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	05 Nov 2020 21:43:08
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	05 Nov 2020 21:41:40
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered empty.	System	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '2'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:46
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:55:51
Query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:56:09
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 14:55:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:55:53
User opened query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:44:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

None

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:46
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 03:36:00
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' answered with 'No ConMeds were taken for this SAE as per Clarification notes on 04Nov2020 in EMR and response has been updated accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 22:12:48
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 22:11:06
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 22:11:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medication that was used for this AE. Please update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 13:13:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:33:39
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:58:08
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Con Procedure indication has been updated to AE as per query.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:01:54
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	05 Nov 2020 21:43:08
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 21:43:08
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	05 Nov 2020 21:41:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

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 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'pt with open surgery and post op recovery ongoing'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:46
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Narrative = COLOR-FLOW PW DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:57:55
User closed query 'Per DM CLR: Narrative = LV DIASTOLIC DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 15:57:12
Query 'Per DM CLR: Narrative = COLOR-FLOW PW DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ConProc "Echocardiography" has been updated to reflect that is was Color-Flow PW Echocardiography.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:08:25
Query 'Per DM CLR: Narrative = LV DIASTOLIC DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Confirming that LV diastolic dysfunction should NOT be recorded as a separate AE.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:01:20
User opened query 'Per DM CLR: Narrative = COLOR-FLOW PW DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:14:59
User opened query 'Per DM CLR: Narrative = LV DIASTOLIC DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:14:52

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: At time of discharge, subject was started on 'Apixaban' for 'Non-Valvular Atrial Fibrillation'. Please confirm if 'Non-Valvular Atrial Fibrillation' is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If 'Non-Valvular Atrial Fibrillation' is a new finding, please assess whether it meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:04:22
Query 'PV Query: At time of discharge, subject was started on 'Apixaban' for 'Non-Valvular Atrial Fibrillation'. Please confirm if 'Non-Valvular Atrial Fibrillation' is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If 'Non-Valvular Atrial Fibrillation' is a new finding, please assess whether it meets criteria for separate AE/SAE reporting' answered with 'Apixaban is taken for Non-Valvular Atrial Fibrillation prophylaxis following AVR surgery.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 20:31:23
User opened query 'PV Query: At time of discharge, subject was started on 'Apixaban' for 'Non-Valvular Atrial Fibrillation'. Please confirm if 'Non-Valvular Atrial Fibrillation' is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If 'Non-Valvular Atrial Fibrillation' is a new finding, please assess whether it meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 13:52:14
User closed query 'Per DM CLR: Narrative indicates that the subject also had EKG on 29 Oct 20202 and 30 Oct 20202. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 03:38:18
Query 'Per DM CLR: Narrative indicates that the subject also had EKG on 29 Oct 20202 and 30 Oct 20202. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'Concomitant Procedure Log has been updated accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 22:10:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

2064 of 2984

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject also had EKG on 29 Oct 20202 and 30 Oct 20202. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 13:13:59
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:22:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:22:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Relevant diagnostic test results have been recorded in narrative and documented in EMR in progress notes on 18OCT2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 06:21:04

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE -- Relevant procedures/diagnostic tests: Echo 10/19 @ 1623: Left Ventricle: Normal left ventricular systolic function. Ejection fraction estimated at 65 - 70%. Grade 1 (mild) LV diastolic dysfunction. Moderate Concentric hypertrophy. Left Atrium: Left atrium is mildly dilated Aortic Valve: A bicuspid valve cannot be excluded. There is calcification of the aortic valve present. Severe stenosis. Trace regurgitation on color-flow PW Doppler. AV Peak Gradient: 107.0mmHg AV Mean Gradient: 82.0mmHg Aortic Valve Area: 0.49cm2 Pulmonic Valve: Trace regurgitation on color-flow PW Doppler. --- EKG: 10/27/2020 - Abnormal, 10/29/2020 - Abnormal, 10/30/2020 - Abnormal' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 06:19:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Hospital Discharge Summary has been sent as per query.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:47:47
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 15:55:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

2066 of 2984

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pre-admission COVID-19 date of collection, type of test, and results of testing have been recorded in narrative. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 19:29:04
User entered 'PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. SUBJECT WAS TESTED FOR COVID-19 DURING HOSPITAL ADMISSION USING A "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC" TEST WITH COLLECTION DATE ON 27OCT2020 AND RESULTS WERE NEGATIVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:28:16
User entered 'PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:36:11
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:21:59

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED CONSIDERED AS A SERIOUS AE. Subject was tested for COVID-19 during hospital admission using a "SARS-COV-2 (COVID-19) RT-PCR BIOCARTIS - ASYMPTOMATIC"test with collection date on 27OCT2020 and results were negative.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:21:59
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:45:06
Query '(AE #2) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:44:56
User opened query '(AE #2) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:44:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:44:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:44:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

2068 of 2984

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered 'PT WITH SYNCOPE AND SEVERE AORTIC STENOSIS WHICH WAS PRESENT PRIOR TO THE STUDY DRUG PRESENT AND WAS DOCUMENTED DURING THE INITIAL HISTORY AND PHYSICAL BUT SINCE THE SUBSEQUENT EVALUATION LED TO THE OPERATION OCCURRING AFTER THE FIRST DOSE RECEIVED considered as a serious AE' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:33:39
User entered 'Pt with syncope and severe aortic stenosis which was present Prior to the study drug present and was documented during the initial history and physical BUt since the subsequent evaluation led to the operation occurring after the first dose received'	(b) (4), (b) (6)	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1'	System	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1'	System	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 16:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:11:32
User entered '1'	System	05 Nov 2020 21:41:40

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:39:31
User entered 'USA-US079-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	06 Nov 2020 19:39:28

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural haemorrhage, LLT: Intraoperative bleeding - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:26:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:26:45
Data point term sent to Coder	System	05 Nov 2020 22:01:06
User entered 'Increased bleeding intra operative time'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 22:01:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 22:01:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:01:06
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 22:00:47
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered '2'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:02:13
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 23:02:13
User closed query 'PV Query: Did the bleeding cause permanent disability or did it require transfusion or other treatment? If the bleeding did not cause a permanent disability, then another seriousness criterion should be used.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 15:57:08
Query 'PV Query: Did the bleeding cause permanent disability or did it require transfusion or other treatment? If the bleeding did not cause a permanent disability, then another seriousness criterion should be used.' answered with 'Subject required transfusion as recorded in Concomitant procedures.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 19:37:29
User opened query 'PV Query: Did the bleeding cause permanent disability or did it require transfusion or other treatment? If the bleeding did not cause a permanent disability, then another seriousness criterion should be used.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:46:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:02:13
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 23:02:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Related (RELATED)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:56:47
Query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'IP action updated as per query.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:55:05
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:37:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:37:14
User opened query 'PV Query: As the last dose of study drug was given on 14 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:45:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Re-query: Per CDM: Response noted, kindly confirm the procedure line for this AE.Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 04:17:56
Query 'Re-query: Per CDM: Response noted, kindly confirm the procedure line for this AE.Thank you' answered with 'Confirming the Concomitant Procedure Log line for this AE is CP#7.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:59:40
User opened query 'Re-query: Per CDM: Response noted, kindly confirm the procedure line for this AE.Thank you' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 03:37:54
User closed query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 03:37:54
Query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' answered with 'Confirming Concomitant procedure was used of Blood/Platelet/Cryoprecipitate transfusion to employed to treat this SAE as per Clarification Progress Notes in EMR on 04Nov2020 as well as Concomitant Procedure recorded in Con Procedure eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 21:52:31
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 21:49:23
User entered '0' reason for change: New Information	(b) (4), (b) (6)	07 Jan 2021 21:49:23

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Is this AE serious? = Yes. Please review and note that there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 13:10:08
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 13:44:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:44:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 13:43:43
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 15:59:30
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'Con Procedure eCRF has been updated to AE.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:19:22
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:16:01
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 21:49:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	07 Jan 2021 21:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:43:43
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[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 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'PV Query: Since the bleeding was reported as resolved please consider updating the seriousness criterion. If the bleeding did not cause a permanent disability, then another seriousness criterion should be used. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:11:39
Query 'PV Query: Since the bleeding was reported as resolved please consider updating the seriousness criterion. If the bleeding did not cause a permanent disability, then another seriousness criterion should be used. ' answered with 'Seriousness criterion updated as per EMR.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 23:02:45
User opened query 'PV Query: Since the bleeding was reported as resolved please consider updating the seriousness criterion. If the bleeding did not cause a permanent disability, then another seriousness criterion should be used. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:19:33

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT UNDERWENT AVR AND WAS NOTED TO BLEED PROFUSELY AND THE SURGEON FELT THAT THAT THERE WAS NO KNOWN CAUSE OF THE SAME AND RAISED THE POSSIBILITY OF ASSOCIATION OF THE BLEEDING RISK WITH THE USE OF A STUDY PRODUCT. SUBJECT WAS TAKING THE FOLLOWING CONMEDS ON AN ONGOING BASIS PRIOR TO AVR SURGERY: MULTIVITAMIN (CENTRAVITE WITH ANTIOXIDANTS) VITAMIN D1, ZINC, NICOTROL, INCRUSE (UMECLINIDIUM) ATORVASTATIN, MOTRIN(IBUPROFEN), VITAMIN C, FISH OIL ALBUTEROL SULFATE. -- SUBJECT TOOK/WAS ADMINISTERED THE FOLLOWING MEDICATIONS AFTER BEING ADMITTED TO THE HOSPITAL, BETWEEN THE DAY PRIOR TO SURGERY (28OCT2020) AND THE END OF AVR SURGERY: DIPHENHYDRAMINE (BENADRYL), DIAZEPAM (VALIUM) ASPIRIN, FENTANYL (SUBLIMAZE) ,MIDAZOLAM (VERSED), METOPROLOL TARTRATE (LOPRESSOR), ACETAMINOPHEN (TYLENOL). Relevant lab test results are as follow: (1)PTT (12.2 - 14.4 seconds): 10/28/20 = 14.6, 10/29/20 = 17.9, 10/30/20 = 15.1; (2) INR (0.80 - 1.20): 10/28/20 = 1.16, 10/29/20 = 1.52, 10/30/20 = 1.21; (3) PTT (23.4 - 38.9 secs): 10/28/20 = 29.9, 10/29/20 = ND, 10/30/20 = 33.7; (4)HGB (13.0 - 17.0 gm/dL): 10/28/20 = ND, 10/29/20 = 8.8, 10/30/20 = 8.8; (5)HCT (38.7 - 50.0 %): 10/28/20 = ND, 10/29/20 = 24.7, 10/30/20 = 25.1; (6)PLT (135 - 430 x10(3)/mcL): 10/28/20 = ND, 10/29/20 = 127, 10/30/20 = 142' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 02:50:45

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide details of the event of bleeding, duration, amount. history of other bleeding events. Also provide of vitamins and other supplements the subject was taking if applicable, such as Vit E, fish oils, CoQ10, turmeric, etc which could have a blood thinning effect.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:26:40
User closed query 'PV Query: Please assess if Aspirin given on 28 Oct 2020, the day prior to AVR surgery, attributed to the increased intraoperative bleeding.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:26:38
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:26:35

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide details of the event of bleeding, duration, amount, history of other bleeding events. Also provide of vitamins and other supplements the subject was taking if applicable, such as Vit E, fish oils, CoQ10, turmeric, etc which could have a blood thinning effect.' answered with 'As per Operative Report (please refer to pg. 20 of documents sent to Safety Moderna), after the surgical incision had been closed despite heparin reversal with protamine and ACT return to 116 (approximately baseline), there was continued mediastinal bleeding of unknown source with notably very poor clot formation, however despite giving a unit of FFP and platelets, coagulopathy was not corrected and there was significant bleeding from sternal edges. Subject's chest tube output was monitored. TEG study revealed FFP, platelets, and cryoprecipitate, which the surgeon found surprising as the operation was not particularly long and the patient had not described taking any anti-coagulants. Subject's incision was reopened and posterior aortic suture line was over sewn again due to some oozing, but not enough to explain the blood seen and there was continued significant bleeding from mediastinal soft tissues. Over time, this blood continued to thicken. Neither bleeding amount or duration were documented. All ConMeds including supplements that the subject was taking on an ongoing basis prior to the surgery as well as medications taken after admission on 28OCT2020 until/during his surgery were recorded in the narrative.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:18:20
Query 'PV Query: Please assess if Aspirin given on 28 Oct 2020, the day prior to AVR surgery, attributed to the increased intraoperative bleeding.' answered with 'According to the PI's assessment, a single dose of Aspirin taken the day before surgery is probably not solely responsible for the bleeding.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:16
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 06:30:45

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT UNDERWENT AVR AND WAS NOTED TO BLEED PROFUSELY AND THE SURGEON FELT THAT THAT THERE WAS NO KNOWN CAUSE OF THE SAME AND RAISED THE POSSIBILITY OF ASSOCIATION OF THE BLEEDING RISK WITH THE USE OF A STUDY PRODUCT. Subject was taking the following ConMeds on an ongoing basis prior to AVR surgery: MULTIVITAMIN (CENTRAVITE WITH ANTIOXIDANTS) VITAMIN D1, ZINC, NICOTROL, INCRUSE (UMECLINIDIUM) ATORVASTATIN, MOTRIN(IBUPROFEN), VITAMIN C, FISH OIL ALBUTEROL SULFATE. -- Subject took/was administered the following medications after being admitted to the hospital, between the day prior to surgery (28OCT2020) and the end of AVR surgery: diphenhydrAMINE (BENADRYL), diazepam (VALIUM) Aspirin, fentanyl (SUBLIMAZE) midazolam (VERSED), metoprolol tartrate (LOPRESSOR), acetaminophen (TYLENOL).'	(b) (4), (b) (6)	19 Nov 2020 06:30:45
reason for change: Data Entry Error Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Relevant laboratory and diagnostic tests results have been sent to Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 22:26:36
User opened query 'PV Query: Please provide details of the event of bleeding, duration, amount. history of other bleeding events. Also provide of vitamins and other supplements the subject was taking if applicable, such as Vit E, fish oils, CoQ10, turmeric, etc which could have a blood thinning effect.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:45:59
User opened query 'PV Query: Please assess if Aspirin given on 28 Oct 2020, the day prior to AVR surgery, attributed to the increased intraoperative bleeding.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:45:45

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:19
User entered 'Pt underwent AVR and was noted to bleed profusely and the surgeon felt that that there was no known cause of the same and raised the possibility of association of the bleeding risk with the use of a study product .'	(b) (4), (b) (6)	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:01:06

US3602051

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:00:47

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 15:01:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 15:01:31
Data point term sent to Coder	System	30 Dec 2020 15:01:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 15:00:24
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 15:00:24
User entered 'RIB PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:00:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 08:33:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 08:33:29
Data point term sent to Coder	System	06 Nov 2020 17:17:09
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 17:16:44
User entered 'RIB PAIN (BILATERAL) PAIN SCALE: 8/10' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:16:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:59:18

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4) System	06 Nov 2020 14:59:18
User entered 'RIB PAIN (BILATERAL) Pain scale: 8/10' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 14:37:44
User entered 'Rib pain (bilateral)'	(b) (4), (b) (6)	06 Nov 2020 14:37:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
		06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:16:44
User entered '19 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User entered empty.	System	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:16:44
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User entered empty.	System	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
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) (4), (b) (6)	07 Jan 2021 11:21:16
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 'Data updated accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:02:39
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 16:02:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 16:02:23
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 14:36:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 16:43:37
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 16:43:37
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please review response as there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). Query 'Per DM CLR: Please review response as there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Confirming that subject did NOT take medication for this AE as per AE Follow-Up call notes in EMR on 06Nov2020. Other medications taken during this time frame were r/t subject's AVR surgery.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 04:57:57
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 16:46:24
DataPoint Un-verified.	(b) (4), (b) (6)	31 Dec 2020 16:43:37
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:17:22
User opened query 'Per DM CLR: Please review response as there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 15:17:22
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 09:54:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Nov 2020 23:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 14:37:13

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure 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)	31 Dec 2020 05:18:08
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No concomitant procedures were performed to treat this AE and response was updated accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:18:28
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 15:17:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:17:22
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure 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)	30 Dec 2020 09:54:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:08:23
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User entered '0'	System	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
User entered '1'	System	06 Nov 2020 14:37:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 13:47:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 13:30:36

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:10:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:10:38
User closed query 'Per CDM: Response noted on Diary Dose form. However, kindly provide the Concomitant Log line # to confirm the medication taken for Diary Dose 2, Day 1 (14OCT2020) and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:41:33
Query 'Per CDM: Response noted on Diary Dose form. However, kindly provide the Concomitant Log line # to confirm the medication taken for Diary Dose 2, Day 1 (14OCT2020) and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' answered with 'ConMed on CML#6 was taken for Dose 2 eDiary Day 1.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 21:11:38
User opened query 'Per CDM: Response noted on Diary Dose form. However, kindly provide the Concomitant Log line # to confirm the medication taken for Diary Dose 2, Day 1 (14OCT2020) and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:39:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:46:11

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE, PRODUCTSYNONYM: NICOTROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 18:50:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 18:50:47
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 18:49:36
User entered 'Nicotrol'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User closed query 'Per DM CLR: Please note that Smoking is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:54:12
Query 'Per DM CLR: Please note that Smoking is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Medical Condition has been added to medical history ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:12:00
User opened query 'Per DM CLR: Please note that Smoking is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:35:14
User entered 'Smoking Cessation'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '10'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:25:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:25:00
User entered 'PRN'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN Mar 2020'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:49:24

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: UMECLIDINIUM BROMIDE, PRODUCTSYNONYM: INCRUSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 08:16:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 08:16:53
Data point term sent to Coder	System	06 Nov 2020 17:21:13
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User entered 'INCRUSE (umecliniidum)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: UMECLIDINIUM BROMIDE, PRODUCTSYNONYM: INCRUSE ELLIPTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:54:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:54:44
Data point term sent to Coder	System	17 Sep 2020 18:53:47
User entered 'Incruse Ellipta'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'COPD'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '62.5' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User entered 'Unknown'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty; reason for change New Information	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User entered 'unknown'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:20:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2015'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:53:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:51:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:51:38
Data point term sent to Coder	System	11 Nov 2020 19:50:56
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 19:50:24
User entered 'ATORVASTATIN' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 19:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:25:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:25:45
Data point term sent to Coder	System	17 Sep 2020 18:55:55
User entered 'Atorvastation'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'HLD'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '10'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2011' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 17:21:39
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0' reason for change: New Information	(b) (4), (b) (6)	30 Nov 2020 17:21:39
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:55:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:00:44
Data point term sent to Coder	System	17 Sep 2020 19:00:04
User entered 'Motrin'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Headaches'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '800'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 19:04:05
User entered 'as needed (PRN)' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 23:30:51
User entered 'other (OTHER)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'PRN, 1-2x/month' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 19:04:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	18 Nov 2020 23:30:51
User entered 'PRN'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2005' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 19:03:11
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 19:03:11
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 23:30:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN Jul 2020' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 23:30:51
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User entered empty.	System	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User entered empty.	System	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:44
User entered empty.	System	17 Sep 2020 18:59:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:05:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:05:25
Data point term sent to Coder	System	05 Nov 2020 21:04:35
User entered 'Motrin (ibuprofen)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Headache'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '400'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User entered empty.	System	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User entered empty.	System	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:27
User entered empty.	System	05 Nov 2020 21:03:47

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: OFIRMEV - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 10:11:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 10:11:50
Data point term sent to Coder	System	10 Feb 2021 15:22:26
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 15:22:20
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: OFIRMEV - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:47:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:47:21
Data point term sent to Coder	System	06 Nov 2020 17:42:39
User entered 'acetaminophen (OFIRMEV)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:45:31
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:19:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Indication has been updated to reflect AE and con procedure.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:23:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 15:22:20
User entered 'PAIN CONTROL r/t AVR surgery due to SAE worsening of aortic stenosis' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 15:22:20
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:14:03
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Pain Control'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1,000'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Q6h (2 doses total)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User entered empty.	System	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User entered empty.	System	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:32
User entered empty.	System	06 Nov 2020 17:41:59

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 06:55:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 06:55:08
Data point term sent to Coder	System	26 Feb 2021 03:34:19
Data point term sent to Coder	System	26 Feb 2021 03:31:16
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 03:30:58
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 23:58:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 23:58:08
Data point term sent to Coder	System	27 Jan 2021 20:43:09
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 20:42:58
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:46:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:46:29
Data point term sent to Coder	System	06 Nov 2020 17:45:46
User entered 'acetaminophen (TYLENOL)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

2261 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:01:42
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'This pain is musculoskeletal and connective tissue related due to the incision made to perform Atrial Valve Replacement Surgery right after the surgery (same day).' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 03:36:32
User entered 'PAIN (MUSCULOSKELETAL AND CONNECTIVE TISSUE RELATED chest PAIN DUE TO AVR surgery related INCISION)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 03:34:07
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 03:30:58
User entered 'PAIN (Musculoskeletal and connective tissue related pain due to incision mad during AVR SURGERY)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 03:30:58
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

2263 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match ' (Site from DM). Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match	(b) (4), (b) (6)	28 Jan 2021 16:18:35
' answered with 'Subject took this ConMed following AVR surgery (same day) which required an incision in his midline chest.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:45:26
User entered 'PAIN (Chest, s/p AVR surgery)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 20:42:58
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match	(b) (4), (b) (6)	27 Jan 2021 13:57:35
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Pain'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '650'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:52:46
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:46:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:52:46
User entered 'Q4h PRN' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:46:49
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:45:09
User closed query 'Please confirm if this date should be 31-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 05:45:07
Query 'Please confirm if this date should be 31-Oct-2020 and update data accordingly.' answered with 'Confirming this date, 29Oct2020, is correct as per EMR medications section.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:14:20
User opened query 'Please confirm if this date should be 31-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:40:37
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User entered empty.	System	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User entered empty.	System	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:38
User entered empty.	System	06 Nov 2020 17:45:08

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Nov 2020 08:11:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Nov 2020 08:11:28
Data point term sent to Coder	System	06 Nov 2020 17:52:55
User entered 'apixaban (ELIQUIS)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Non-valvular Atrial Fibrillation'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Q12h'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:08:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:08:27
Data point term sent to Coder	System	06 Nov 2020 17:57:07
User entered 'aspirin (tablet)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UNK (taken prior to Atrial Valve Replacement surgery)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '325'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User entered empty.	System	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User entered empty.	System	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:48
User entered empty.	System	06 Nov 2020 17:56:35

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ECOTRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:08:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:08:27
Data point term sent to Coder	System	06 Nov 2020 17:58:07
User entered 'aspirin (ECOTRIN)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 's/p cardiac surgery'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '81'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 17:57:58

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: MONOBACTAMS, PRODUCT: AZTREONAM, PRODUCTSYNONYM: AZACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:12:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:12:28
Data point term sent to Coder	System	06 Nov 2020 18:09:25
User entered 'aztreonam (AZACTAM) / D5W'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Anti-biotic (surgical prophylaxis)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1/50'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'g/mL'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'q8h'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User entered empty.	System	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User entered empty.	System	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:34:57
User entered empty.	System	06 Nov 2020 18:08:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:13:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:13:28
Data point term sent to Coder	System	06 Nov 2020 18:27:45
User entered 'Bacitracin (ointment)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Incision care'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'application'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'twice daily (BID)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:26:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:48:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:48:22
Data point term sent to Coder	System	06 Nov 2020 18:33:58
User entered 'diphenhydrAMINE (BENADRYL)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Insomnia'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '25'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:01:03
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Three times' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:01:03
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:01:03
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:01:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:01:30
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User entered empty.	System	18 Nov 2020 23:01:03
User entered '1'	System	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User entered empty.	System	18 Nov 2020 23:01:03
User entered '1'	System	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:08
User entered empty.	System	18 Nov 2020 23:01:03
User entered '804 (804)'	System	06 Nov 2020 18:33:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL, PRODUCTSYNONYM: SUBLIMAZE [FENTANYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:55:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:55:23
Data point term sent to Coder	System	06 Nov 2020 18:48:19
User entered 'fentaNYL (SUBLIMAZE)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Pain control (RVA surgery)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0.05'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Two (2) times'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User entered empty.	System	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User entered empty.	System	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:25
User entered empty.	System	06 Nov 2020 18:48:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:16:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:16:28
Data point term sent to Coder	System	06 Nov 2020 19:02:43
User entered 'ferrous sulfate 325 (65 Fe) MG tablet'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Anemia From Inadequate Iron in the Body (s/p AVR)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '325'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 19:01:53

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:30
Data point term sent to Coder	System	06 Nov 2020 19:31:27
User entered 'ketorolac (TORADOL)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:31:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 19:31:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 19:31:07
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:30:34
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Pain control (s/p RVA surgery)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '15'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User entered empty.	System	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User entered empty.	System	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:42
User entered empty.	System	06 Nov 2020 19:30:34

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: PETHIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:23:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:23:28
Data point term sent to Coder	System	06 Nov 2020 19:34:33
User entered 'meperidine (DEMEROL)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Shivering (s/p RVA surgery)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '12.5'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'two (2) times'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User entered empty.	System	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User entered empty.	System	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:48
User entered empty.	System	06 Nov 2020 19:33:50

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:23:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:23:27
Data point term sent to Coder	System	06 Nov 2020 19:44:47
User entered 'metoprolol tartrate (LOPRESSOR)	(b) (4), (b) (6)	06 Nov 2020 19:44:26
,		

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'R/t to RVA surgery'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '12.5'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User entered empty.	System	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User entered empty.	System	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:35:58
User entered empty.	System	06 Nov 2020 19:44:26

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:29
Data point term sent to Coder	System	06 Nov 2020 20:00:04
User entered 'midazolam (VERSED) 10 MG/2ML'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'sedation (r/t RVA surgery'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '10/2'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg/mL'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User entered empty.	System	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User entered empty.	System	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:04
User entered empty.	System	06 Nov 2020 19:59:12

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:28
Data point term sent to Coder	System	06 Nov 2020 20:03:11
User entered 'morphine'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Moderate pain (r/t RVA surgery)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 20:02:49
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:02:49
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 20:02:13
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:02:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:02:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:02:49
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:02:13
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:02:49
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User entered empty.	System	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User entered empty.	System	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:08
User entered empty.	System	06 Nov 2020 20:02:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:28
Data point term sent to Coder	System	06 Nov 2020 20:05:13
User entered 'morphine'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:04:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:04:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:04:29
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:04:21
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Severe pain (8-10) r/t RVA surgery'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User entered empty.	System	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User entered empty.	System	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User entered empty.	System	06 Nov 2020 20:04:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:10:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:10:00
Data point term sent to Coder	System	26 Feb 2021 03:38:20
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 03:37:57
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 00:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 00:17:33
Data point term sent to Coder	System	29 Jan 2021 15:52:02
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 15:51:17
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:14:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:14:27
Data point term sent to Coder	System	06 Nov 2020 20:10:18
User entered 'ondansetron (ZOFRAN) injection'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 15:50:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 15:50:39
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:02:21
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 21:02:49
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'Indication has been updated as per query.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 03:38:19
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 03:37:57
User entered 'Prophylaxis for NAUSEA/VOMITING (S/P AVR SURGERY)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 03:37:57
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:58:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:18:51

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no 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 AE eCRF.'	(b) (4), (b) (6)	29 Jan 2021 15:59:34
answered with 'ConMed was administered to prevent nausea/vomiting following AVR surgery.' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 15:51:17
User entered 'NAUSEA/VOMITING (s/p AVR surgery)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 15:51:17
User opened query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:00:53
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Nausea/vomiting'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '4'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'q6h, PRN'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:12:37
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User entered empty.	System	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User entered empty.	System	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:12
User entered empty.	System	06 Nov 2020 20:09:46

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:10:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:10:28
Data point term sent to Coder	System	06 Nov 2020 20:12:23
User entered 'oxyCODONE immediate release (ROXICODONE)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Pain'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:11:28

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE EDISYLATE, PRODUCTSYNONYM: COMPAZINE [PROCHLORPERAZINE EDISYLATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:14:50
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 Mar 2021 09:14:50
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36
Data point term sent to Coder	System	28 Jan 2021 17:51:59
Coding entries removed.	(b) (4), (b) (6)	28 Jan 2021 17:51:17
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH PIPERAZINE STRUCTURE, PRODUCT: PROCHLORPERAZINE EDISYLATE, PRODUCTSYNONYM: COMPAZINE [PROCHLORPERAZINE EDISYLATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 08:13:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 08:13:24
Data point term sent to Coder	System	18 Nov 2020 23:20:49
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 23:20:22
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 23:20:22
User entered 'Prochlorperazine Edisylate (COMPAZINE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:17:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:17:55
Data point term sent to Coder	System	18 Nov 2020 23:16:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
Data point term sent to Coder	System	18 Nov 2020 23:14:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:09:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:09:30
Data point term sent to Coder	System	06 Nov 2020 20:16:37
User entered 'polyethylene glycol (MIRALAX) (packet)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE/ Con Proc as there is an Con Proc recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:35:30
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE/ Con Proc as there is an Con Proc recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' answered with 'Field has been updated to "No."' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:02:53
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:02:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 18:02:26
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE/ Con Proc as there is an Con Proc recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:10:42
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:51:17
User entered 'UNKNOWN (administered during RVA SURGERY)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 17:51:17
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Unknown (R/t RVA SURGERY)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'Constipation (s/p RVA surgery)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '17'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'g (g)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User entered empty.	System	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '1'	System	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User entered empty.	System	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '1'	System	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:40
User entered empty.	System	18 Nov 2020 23:20:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	18 Nov 2020 23:15:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 23:14:17
User entered '804 (804)'	System	06 Nov 2020 20:16:29

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:15:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:15:41
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36
Data point term sent to Coder	System	10 Feb 2021 15:38:38
Data point term sent to Coder	System	10 Feb 2021 15:26:30
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 15:26:29
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:01:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:01:29
Data point term sent to Coder	System	06 Nov 2020 20:18:40
User entered 'traMADol (ULTRAM)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User closed query 'Per DM CLR: The corresponding recorded AE 4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:01:02
Query 'Per DM CLR: The corresponding recorded AE 4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' answered with 'This was ConMed not taken/indicated for AE #4, this ConMed was taken following AVR surgery.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 17:48:23
User opened query 'Per DM CLR: The corresponding recorded AE 4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:11:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:22:09
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Indication has been updated to include location, cause, and related AE.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:38:51
User entered 'MODERATE PAIN (4-7) IN CHEST R/T S/P AVR SURGERY due to worsening of aortic stenosis' reason for change: Per Query Resolution DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 15:38:14
	(b) (4), (b) (6)	10 Feb 2021 15:26:29
User entered 'MODERATE PAIN (4-7) in chest r/t AVR surgery' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 15:26:29
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:14:26

PRODUCTION RELEASE (v12.003
EAB) (1725)

2591 of 2984

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Moderate pain (4-7)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '50'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User entered empty.	System	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User entered empty.	System	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:45
User entered empty.	System	06 Nov 2020 20:18:32

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:19:31
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:09:36
Data point term sent to Coder	System	10 Feb 2021 15:41:43
Data point term sent to Coder	System	10 Feb 2021 15:40:42
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 15:39:57
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:00:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:00:27
Data point term sent to Coder	System	06 Nov 2020 20:22:46
User entered 'vancomycin (VANCOCIN) 1 g in D5W (5% Soln) 250 mL'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 04:21:20
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Indication has been updated to reflect medical condition ConMed was used to prevent as well as related AE.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:42:21
User entered 'ANTI-BIOTIC to prevent infection r/t ARV SURGERY DUE TO WORSENING OF AORTIC STENOSIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 15:41:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 15:39:57
User entered 'ANTI-BIOTIC r/t ARV surgery due to worsening of aortic stenosis' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 15:39:57
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of Drug Class or Mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:14:13
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Anti-biotic'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1/250'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'g/mL'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'q12h'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '29 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User entered empty.	System	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User entered empty.	System	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:50
User entered empty.	System	06 Nov 2020 20:22:16

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:59:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:59:28
Data point term sent to Coder	System	06 Nov 2020 20:25:53
User entered 'warfarin (COUMADIN)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Anticoagulant (s/p AVR surgery)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '2.5'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '31 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User entered empty.	System	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User entered empty.	System	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:58
User entered empty.	System	06 Nov 2020 20:25:21

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:59:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 06:59:29
Data point term sent to Coder	System	06 Nov 2020 20:26:55
User entered 'warfarin (COUMADIN)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Anticoagulant (s/p AVR surgery)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User entered empty.	System	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User entered empty.	System	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:03
User entered empty.	System	06 Nov 2020 20:26:44

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 23:42:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 23:42:40
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 20:30:39
User entered 'Albuterol Sulfate'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'COPD exacerbation/wheezing'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '90'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'ug (ug)'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2015'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:30:27

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:05:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:05:01
Data point term sent to Coder	System	18 Nov 2020 21:09:30
User entered 'diazepam (VALIUM)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Unknown'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '28 Oct 2020'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User entered empty.	System	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User entered empty.	System	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:11
User entered empty.	System	18 Nov 2020 21:08:52

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:03
Data point term sent to Coder	System	18 Nov 2020 23:24:52
User entered 'Vitamin C'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'General good health'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '500'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2016'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 23:24:01

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:08:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:08:52
Data point term sent to Coder	System	18 Nov 2020 23:25:55
User entered 'Fish Oil'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'General good health'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1000'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2018'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 23:24:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
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.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:51:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:51:58
Data point term sent to Coder	System	18 Nov 2020 23:27:58
User entered 'Multivitamin (Centravite with antioxidants)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'General good health'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2015'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 23:26:56

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
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 D1 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:02
Data point term sent to Coder	System	18 Nov 2020 23:28:59
User entered 'Vitamin D1'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'General good health'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '5000'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'IU (IU)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'every week (QS)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:40:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN UNK 2016'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	18 Nov 2020 23:40:23
User entered '804 (804)'	System	18 Nov 2020 23:28:13

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:36:01
Data point term sent to Coder	System	18 Nov 2020 23:29:59
User entered 'Zinc'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'General good health'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '50'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'every other day (QOD)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN Jun 2020'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 23:29:18

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:58:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:58:54
Data point term sent to Coder	System	18 Nov 2020 23:36:04
User entered 'Acyclovir'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Genital herpes (outbreak)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '800'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN Jul 2020'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'UN Jul 2020'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:27
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User entered '1'	System	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User entered '1'	System	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:10:58
User entered '804 (804)'	System	18 Nov 2020 23:35:15

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN, PRODUCTSYNONYM: ZOCOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Jan 2021 15:52:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 15:52:05
Data point term sent to Coder	System	20 Jan 2021 15:51:24
User entered 'Simvastatin (Zocor)'	(b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
	(b) (4)	
User entered '20' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 21:49:00
User entered '10'	(b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 15:51:22

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:10:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:19
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 19:00:08

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:34:54

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Aortic Valve Replacement Surgery'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:34:54

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 14:45:30
User entered 'Medical History (MH)'	(b) (4), (b) (6)	05 Nov 2020 21:34:54

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:34:54

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:14:50

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Color-Flow PW ECHOCARDIOGRAM' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:05:51
User entered 'Echocardiogram'	(b) (4), (b) (6)	06 Nov 2020 14:14:50

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 14:47:12
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:28:37
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'Indication has been updated to reflect condition Aortic Stenosis in subject Med Hx.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 13:26:33
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 13:26:19
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:40:31
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	06 Nov 2020 14:14:50

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:14:50

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:17:04

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Electrocardiogram (EKG)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:17:04

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:17:16
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	06 Nov 2020 14:17:04

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:17:04

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:39

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Cardiac Catheterization'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:39

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:17:43
User entered 'Medical History (MH)'	(b) (4), (b) (6)	06 Nov 2020 14:25:39

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:53:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:39

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:49:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Physical Therapy (following AVR surgery prior to discharge)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:49:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:18:09
User entered 'Medical History (MH)'	(b) (4), (b) (6)	09 Nov 2020 14:49:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:49:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:09:25

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Physical Therapy (prior to AVR surgery)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:09:25

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:18:25
User entered 'Medical History (MH)'	(b) (4), (b) (6)	09 Nov 2020 15:09:25

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:09:25

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:20:18

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'BLOOD/PLATELET/CRYOPRECIPITATE TRANSFUSION (intraoperative, AVR surgery)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:21:13
User entered 'Blood/platelet/cryoprecipitate transfusion.'	(b) (4), (b) (6)	09 Nov 2020 15:20:18

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:15:12
User entered 'Medical History (MH)'	(b) (4), (b) (6)	09 Nov 2020 15:20:18

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:20:18

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:08:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Electrocardiogram (EKG)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:08:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:16:29
User entered 'Medical History (MH)'	(b) (4), (b) (6)	07 Jan 2021 22:08:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:08:48

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:09:36

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:10:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Electrocardiogram (EKG)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:09:36

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:10:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:16:52
User entered 'Medical History (MH)'	(b) (4), (b) (6)	07 Jan 2021 22:09:36

US3602051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:10:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 22:09:36

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '06/Nov/2020 19:40'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '18/Nov/2020 10:58'	System	18 Nov 2020 15:58:23

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 15:58:23

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '19/Nov/2020 13:31'	System	19 Nov 2020 18:31:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 18:31:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '20/Nov/2020 11:26'	System	20 Nov 2020 16:26:52

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 16:26:52

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '02/Dec/2020 08:12'	System	02 Dec 2020 13:12:05

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:36:38
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:56:08
User entered '1'	(b) (4), (b) (6)	02 Dec 2020 13:12:05

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'USA-US079-2020-MRNA-1273-P301000004'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'No (N)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Yes (Y)'	System	06 Nov 2020 19:39:28
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
Un-reviewed for Safety.	System	01 Dec 2020 23:02:13
User entered 'Yes (Y)'	System	01 Dec 2020 23:02:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'No (N)'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Bindu'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'Balani'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '20 Prospect Avenue' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered 'Hackensack' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered 'Hackensack'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:40:18
User entered 'NJ'	System	06 Nov 2020 19:38:38

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:11:56
User entered empty.	System	01 Dec 2020 23:02:13
User entered '07601' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 17:56:03
Un-reviewed for Safety.	System	19 Nov 2020 18:31:38
User entered empty.	System	19 Nov 2020 18:31:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:31:13
User entered '07601'	(b) (4), (b) (6)	19 Nov 2020 15:22:09

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:58:12
User entered 'US'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
	(b) (4)	
User entered '6'	System	08 Jan 2021 21:36:35
User entered '5'	System	02 Dec 2020 13:12:05
User entered '4'	System	20 Nov 2020 16:26:52
User entered '3'	System	19 Nov 2020 18:31:38
User entered '2'	System	18 Nov 2020 15:58:23
User entered '1'	System	06 Nov 2020 19:40:33

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:10:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
User entered '08/Jan/2021 16:36'	(b) (4) System	08 Jan 2021 21:36:35

US3602051

Folder: SAE USA-US079-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:10:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:09:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:36:38
User entered '1'	(b) (4), (b) (6)	08 Jan 2021 21:36:35