

US3752173 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:58

All time stamps listed in this document are displayed in GMT

US3752173

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:58

[Participant ID](#)

US3752173

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

US3752173

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
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	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3752173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3752173

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:58

Were any significant conditions reported?

Yes ☒

No ☐

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

Condition	BILATERAL HEARING LOSS
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)	

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

Condition	HYPERCHOLESTEROLEMIA
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)	

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

Condition	MYOCARDIAL INFARCTION
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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)	

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

Condition	CHOLECYSTECTOMY FOR CHOLECYSTITIS
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

Condition	GERD/REFLUX
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

Condition	GOUT (LOCATION UNKNOWN)
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)	

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

Condition	LOW BACK PAIN
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)	

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

Condition	BASAL CELL CANCER ON FACE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

Condition	PROSTATE ENLARGEMENT
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

Condition	ISLAND PETICOH TRANSPLANT LEFT HAND
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	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

Condition	RECONSTRUCTIVE LEFT HAND SURGERY
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

Condition	CHOLECYSTITIS
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

Condition	CARDIOMYOPATHY
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)	

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

Condition	HYPERTENSION
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)	

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

Condition	CARDIAC CATHETERIZATION
Start date (dd MMM yyyy)	6 NOV 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	06 NOV 2015
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2015
Start Year (derived)	2015
Stop Month and Year (derived)	NOV 2015
Stop Year (derived)	2015

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Height (<i>xxx.x</i>)	70.0 in
Weight (<i>xxx.x</i>)	195.1 lb
BMI (<i>xxx.x</i>)	28.05247 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)	

US3752173

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3752173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187144

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 ☒

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

Height	ND - Not Done
Weight	ND - Not Done

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3752173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

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.

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 20 AUG 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 10:46

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

US3752173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 AUG 2020

Collection time (00:00-23:59)

10:29 (24 HR)

Collection date and time (derived)

20 AUG 2020 10:29

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:58

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:27	20 AUG 2020 10:27
Nasopharyngeal Swab 2	No		

US3752173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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 AUG 2020 11:24

PC Open Date & Time

20 AUG 2020 11:06

PC Close Date & Time

20 AUG 2020 13:36

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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 98.2 °F

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

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

PC Time Stamp	20 AUG 2020 18:23
PC Open Date & Time	20 AUG 2020 14:31
PC Close Date & Time	21 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

94.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 20:38

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:35

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:23

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

97.4 °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

24 AUG 2020 20:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 19:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 11:25

PC Open Date & Time

20 AUG 2020 11:06

PC Close Date & Time

20 AUG 2020 13:36

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

20 AUG 2020 18:24

PC Open Date & Time

20 AUG 2020 14:31

PC Close Date & Time

21 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

21 AUG 2020 20:39

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

22 AUG 2020 19:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

23 AUG 2020 21:24

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

24 AUG 2020 20:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 20:07

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

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

26 AUG 2020 19:20

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 11:26
PC Open Date & Time	20 AUG 2020 11:06
PC Close Date & Time	20 AUG 2020 13:36

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 18:25
PC Open Date & Time	20 AUG 2020 14:31
PC Close Date & Time	21 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	21 AUG 2020 20:40
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	22 AUG 2020 19:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	23 AUG 2020 21:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	24 AUG 2020 20:38
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	25 AUG 2020 20:08
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	26 AUG 2020 19:21
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3752173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:10
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:20
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3752173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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)	18 SEP 2020
What was the treatment time? (00:00-23:59)	11:00 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 11:00
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

US3752173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

18 SEP 2020

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

10:25 (24 HR)

Collection date and time (derived)

18 SEP 2020 10:25

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:58

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:23	18 SEP 2020 10:23
Nasopharyngeal Swab 2	No		

US3752173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 18 SEP 2020 11:30

PC Open Date & Time 18 SEP 2020 11:20

PC Close Date & Time 18 SEP 2020 13:50

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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 97.5 °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 19:37
PC Open Date & Time	18 SEP 2020 14:45
PC Close Date & Time	19 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

99.7 °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

19 SEP 2020 19:20

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 19:18

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 11:31

PC Open Date & Time

18 SEP 2020 11:20

PC Close Date & Time

18 SEP 2020 13:50

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

18 SEP 2020 19:33

PC Open Date & Time

18 SEP 2020 14:45

PC Close Date & Time

19 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

19 SEP 2020 19:21

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

20 SEP 2020 19:18

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

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

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

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

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

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

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

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

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:32
PC Open Date & Time	18 SEP 2020 11:20
PC Close Date & Time	18 SEP 2020 13:50

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 19:38
PC Open Date & Time	18 SEP 2020 14:45
PC Close Date & Time	19 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

Yes ☐	
PC Time stamp	19 SEP 2020 19:23
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

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 ☒

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

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 ☐

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

		Yes ☐
PC Time stamp		
PC Open Date & Time		24 SEP 2020 12:00
PC Close Date & Time		25 SEP 2020 11:59

US3752173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:35 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:35
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3752173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:45 (24 HR)
Collection date and time (derived)	23 OCT 2020 10:45

US3752173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

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

EARLY TERMINATION DUE TO
DEATH

If Contact Not Made, please provide Comments

US3752173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

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☐

US3752173

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:58

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3752173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

AEID	USA-US113-2020-MRNA-1273-P30 1000007
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 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	True
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	
v6.020 DTW (1102)	135 of 1315

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

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	SUBJECT'S DAUGHTER CALLED THE SITE ON 02 NOV 2020 AT 8:00 AND TO REPORT THAT THE SUBJECT HAD DIED OF A "MASSIVE HEART ATTACK" ON 01 NOV 2020
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)	

v6.020 DTW (1102)

136 of 1315

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:58

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

Yes ☒

No ☐

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

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	FISH OIL
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS FOR CARDIAC DISEASE
Dose per administration	1200
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

	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 MAY 2005	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

	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 JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS FOR CARDIAC DISEASE
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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 ☒	

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	CARVEDILOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐ Intraocular ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

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 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
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 ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	SYMBICORT
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	160/4.5
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	FLUTICASONE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	ALLOPURINOL
Prophylaxis	Yes ☐ No ☒
Indication	GOUT
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	ENLARGED PROSTATE
Dose per administration	0.045
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

	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 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 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	☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	0.5 MG/3 MG
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

	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 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	1200
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

	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 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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	☒

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

	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 FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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 ☒	

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

Name of Medication	SEASONAL INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS FOR SEASONAL INFLUENZA
Dose per administration	0.5
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 ☐

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		20 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	☐

US3752173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:58

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

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

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

Date of study discontinuation/completion (dd MMM yyyy) 01 NOV 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☒
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

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

If reason for discontinuation is Death, main cause of death

Adverse event	☒
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 01 NOV 2020

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

SAEID	USA-US113-2020-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	9601 BAPTIST HEALTH DRIVE,SUITE 310
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72022
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:58

SAEID	USA-US113-2020-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	9601 BAPTIST HEALTH DRIVE,SUITE 310
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72022
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	03/NOV/2020 08:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3752173 (Prod: Baptist Health Center for Clinical Research)

US3752173

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:58

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3752173'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 15:09:50

US3752173

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:56:37

US3752173

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 15:09:51

US3752173

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 15:56:37

US3752173

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	20 Aug 2020 15:56:37

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 15:09:53

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Age](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '77'	System	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:04:35
User entered 'Female (F)'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:58

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 15:09:51

US3752173

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:52:59

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 19:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Aug 2020 19:55:20
Data point term sent to Coder	System	20 Aug 2020 19:53:48
User entered 'Cataracts'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:53:18

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:21
Data point term sent to Coder	System	20 Aug 2020 19:53:49
User entered 'Bilateral hearing loss'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2005'	System	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:53:42

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:55:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:55:58
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:54:02

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:16:45
Query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:07:48
User opened query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 23:21:56
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 19:55:22
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'Myocardial infarction'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Oct 2020 13:07:38
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Oct 2020 13:07:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:07:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:07:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Oct 2020 13:07:38
User entered empty.	System	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Oct 2020 13:07:38
User entered empty.	System	20 Aug 2020 19:54:34

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:41:45
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 15:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:20:25
Query 'Per MM, please expand the abbreviation ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:18:55
Data point term sent to Coder	System	05 Oct 2020 15:18:53
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 15:18:50
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:18:50
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 02:34:14
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)	20 Aug 2020 19:57:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:31
Data point term sent to Coder	System	20 Aug 2020 19:55:52
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2005'	System	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:54:57

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
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)	19 Oct 2020 19:16:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:53:54
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:53:54
Data point term sent to Coder	System	16 Oct 2020 16:21:26
User entered 'CHOLECYSTECTOMY for cholecystitis' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:20:29
Data point term sent to Coder	System	16 Oct 2020 16:20:25
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:19:35
User entered 'CHOLECYSTECTOMY (unknown associated condition)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:19:35
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 'UPDATED' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:14:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 23:22:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
Data point term sent to Coder	System	20 Aug 2020 19:55:54
User entered 'Cholecystectomy'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:55:23

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
Data point term sent to Coder	System	20 Aug 2020 19:55:59
User entered 'GERD/reflux'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2002'	System	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:55:45

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout, unspecified - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:33:32
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:33:32
User closed query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:15:39
Data point term sent to Coder	System	28 Oct 2020 16:07:16
Query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:06:41
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 16:06:34
User entered 'GOUT (location unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:06:34
User opened query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:00:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 19:58:20
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 19:57:00
User entered 'Gout'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:56:07

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
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: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
Data point term sent to Coder	System	20 Aug 2020 19:57:02
User entered 'Low back pain'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:56:25

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma face - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:32:28
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:32:28
Data point term sent to Coder	System	20 Aug 2020 20:00:09
User entered 'Basal cell cancer on face'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 19:59:24

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:59:21
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:59:21
Data point term sent to Coder	System	20 Aug 2020 20:00:12
User entered 'Prostate enlargement'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2004'	System	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:59:45

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 02:43:35
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 02:43:35
Data point term sent to Coder	System	20 Aug 2020 20:01:15
User entered 'Island Peticoh Transplant left hand'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:00:32

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb reconstructive surgery, LLT: Limb reconstructive surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:52:56
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 10:52:56
Data point term sent to Coder	System	20 Aug 2020 20:01:15
User entered 'Reconstructive left hand surgery'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '1979'	System	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '1979'	System	20 Aug 2020 20:00:59

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:15:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:15:39
Data point term sent to Coder	System	13 Oct 2020 13:14:11
User entered 'CHOLECYSTITIS'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Oct 2020 13:13:55

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 17:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 17:05:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 16:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 16:50:46
Data point term sent to Coder	System	18 Nov 2020 16:49:38
User entered 'CORONARY ARTERY DISEASE'	Amanda Horn (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'UN Dec 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Dec 2015'	System	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:49:14

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 16:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 16:51:45
Data point term sent to Coder	System	18 Nov 2020 16:50:40
User entered 'CARDIOMYOPATHY'	Amanda Horn (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:50:31

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 16:52:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 16:52:47
Data point term sent to Coder	System	18 Nov 2020 16:51:40
User entered 'HYPERTENSION'	Amanda Horn (b) (4)	18 Nov 2020 16:51:08
	(b) (4)	

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Nov 2020 16:51:21
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Nov 2020 16:51:08
User entered empty.	Amanda Horn (b) (4)	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 16:51:21
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:51:08

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 16:54:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 16:54:45
Data point term sent to Coder	System	18 Nov 2020 16:53:45
User entered 'CARDIAC CATHETERIZATION'	Amanda Horn (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '6 Nov 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '06 Nov 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Nov 2015'	System	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Nov 2015'	System	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '2015'	System	18 Nov 2020 16:53:02

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:15'	System	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.05247'	System	17 Sep 2020 00:15:57
User entered '28.1'	System	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:25:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '097.9' F	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:51:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '061'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '16'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '116'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '074'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:02:11

US3752173

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:29:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:02:21

US3752173

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:29:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:51:30
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:02:21

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:58

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:08:12

US3752173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:08:12

US3752173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 20:08:12

US3752173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	20 Aug 2020 20:08:12

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 15:40:23

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:51:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:51:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 15:40:23
User entered '187144' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 15:40:23

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 15:40:23

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 15:25:14
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:43:52

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:15'	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:25:32
User entered '097.9' F	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:16
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:16
User entered '061' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:16
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:16
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:16
User entered '074' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

[Height](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:58

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 20:09:42
User entered '11:20'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:20'	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:46
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:46
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:46
User entered '110' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 20:10:46
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:26:06
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:54:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:54:31
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 20:49:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:10:57

US3752173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:54:31
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:10:57

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '10:46'	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:46'	System	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 15:57:50

US3752173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:11:28

US3752173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:11:28

US3752173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:29'	(b) (4), (b) (6)	20 Aug 2020 20:11:28

US3752173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:29'	System	20 Aug 2020 20:11:28

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '10:27'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:27'	System	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:11:46

US3752173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:12:02

US3752173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:12:02

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:23:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d' User entered 'Yes (Y)'	System	20 Aug 2020 16:25:25
	System	20 Aug 2020 16:25:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:09', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d' User entered '98.7'	System	20 Aug 2020 16:25:25
	System	20 Aug 2020 16:25:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered 'No (N)'	System	20 Aug 2020 16:25:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered '20 Aug 2020 11:24'	System	20 Aug 2020 16:25:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:22:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered 'Yes (Y)'	System	20 Aug 2020 23:23:42

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered '98.2'	System	20 Aug 2020 23:23:42

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered 'No (N)'	System	20 Aug 2020 23:23:42

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered '20 Aug 2020 18:23'	System	20 Aug 2020 23:23:42

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:37:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered 'Yes (Y)'	System	22 Aug 2020 01:38:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered '94.2'	System	22 Aug 2020 01:38:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered 'No (N)'	System	22 Aug 2020 01:38:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered '21 Aug 2020 20:38'	System	22 Aug 2020 01:38:25

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:16', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered 'Yes (Y)'	System	23 Aug 2020 00:35:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered '98.0'	System	23 Aug 2020 00:35:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered 'No (N)'	System	23 Aug 2020 00:35:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:47', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered '22 Aug 2020 19:35'	System	23 Aug 2020 00:35:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:17', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered 'Yes (Y)'	System	24 Aug 2020 02:24:39

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered '97.2'	System	24 Aug 2020 02:24:39

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered 'No (N)'	System	24 Aug 2020 02:24:39

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered '23 Aug 2020 21:23'	System	24 Aug 2020 02:24:39

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered 'Yes (Y)'	System	25 Aug 2020 01:35:13

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered '97.4'	System	25 Aug 2020 01:35:13

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered 'No (N)'	System	25 Aug 2020 01:35:13

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered '24 Aug 2020 20:35'	System	25 Aug 2020 01:35:13

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:21', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered 'Yes (Y)'	System	26 Aug 2020 01:06:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered '97.6'	System	26 Aug 2020 01:06:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered 'No (N)'	System	26 Aug 2020 01:06:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered '25 Aug 2020 20:06'	System	26 Aug 2020 01:06:49

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered 'Yes (Y)'	System	27 Aug 2020 00:19:43

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered '97.7'	System	27 Aug 2020 00:19:43

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered 'No (N)'	System	27 Aug 2020 00:19:43

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered '26 Aug 2020 19:19'	System	27 Aug 2020 00:19:43

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'None (1)'	System	20 Aug 2020 16:26:47

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:56', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'No (N)'	System	20 Aug 2020 16:26:47

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'No (N)'	System	20 Aug 2020 16:26:47

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'None (1)'	System	20 Aug 2020 16:26:47

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered '20 Aug 2020 11:25'	System	20 Aug 2020 16:26:47

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:10', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'None (1)'	System	20 Aug 2020 23:24:53

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:19', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'No (N)'	System	20 Aug 2020 23:24:53

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'No (N)'	System	20 Aug 2020 23:24:53

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf' User entered 'None (1)'	System	20 Aug 2020 23:24:53

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 23:24:53

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 01:39:09

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'No (N)'	System	22 Aug 2020 01:39:09

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'No (N)'	System	22 Aug 2020 01:39:09

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'None (1)'	System	22 Aug 2020 01:39:09

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered '21 Aug 2020 20:39'	System	22 Aug 2020 01:39:09

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:05', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 00:36:35

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:10', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'No (N)'	System	23 Aug 2020 00:36:35

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'No (N)'	System	23 Aug 2020 00:36:35

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'None (1)'	System	23 Aug 2020 00:36:35

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:30', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered '22 Aug 2020 19:36'	System	23 Aug 2020 00:36:35

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'None (1)'	System	24 Aug 2020 02:24:45

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'No (N)'	System	24 Aug 2020 02:24:45

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'No (N)'	System	24 Aug 2020 02:24:45

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'None (1)'	System	24 Aug 2020 02:24:45

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered '23 Aug 2020 21:24'	System	24 Aug 2020 02:24:45

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'None (1)'	System	25 Aug 2020 01:36:32

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'No (N)'	System	25 Aug 2020 01:36:32

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'No (N)'	System	25 Aug 2020 01:36:32

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'None (1)'	System	25 Aug 2020 01:36:32

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered '24 Aug 2020 20:36'	System	25 Aug 2020 01:36:32

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'None (1)'	System	26 Aug 2020 01:07:19

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:58', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'No (N)'	System	26 Aug 2020 01:07:19

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'No (N)'	System	26 Aug 2020 01:07:19

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'None (1)'	System	26 Aug 2020 01:07:19

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered '25 Aug 2020 20:07'	System	26 Aug 2020 01:07:19

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'None (1)'	System	27 Aug 2020 00:20:18

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'No (N)'	System	27 Aug 2020 00:20:18

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'No (N)'	System	27 Aug 2020 00:20:18

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'None (1)'	System	27 Aug 2020 00:20:18

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered '26 Aug 2020 19:20'	System	27 Aug 2020 00:20:18

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e' User entered 'None (0)'	System	20 Aug 2020 23:22:40
	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:32', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e' User entered 'None (0)'	System	20 Aug 2020 23:22:40
	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e' User entered 'None (0)'	System	20 Aug 2020 23:22:40
	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:26:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'No (N)'	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:26:09', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered '20 Aug 2020 11:26'	System	20 Aug 2020 23:22:40

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c' User entered 'None (0)'	System	20 Aug 2020 23:25:57
	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'No (N)'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered '20 Aug 2020 18:25'	System	20 Aug 2020 23:25:57

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:47', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:40:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'No (N)'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:40:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered '21 Aug 2020 20:40'	System	22 Aug 2020 01:40:14

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'No (N)'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:30', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered '22 Aug 2020 19:37'	System	23 Aug 2020 00:37:32

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:03', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'No (N)'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:56', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered '23 Aug 2020 21:25'	System	24 Aug 2020 02:25:59

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'No interference with activity (1)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:32', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'No (N)'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered '24 Aug 2020 20:38'	System	25 Aug 2020 01:38:28

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'No (N)'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:08:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered '25 Aug 2020 20:08'	System	26 Aug 2020 01:08:09

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:14', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'No (N)'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered '26 Aug 2020 19:21'	System	27 Aug 2020 00:21:20

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:03:56

US3752173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:03:56

US3752173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:04:09

US3752173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:04:09

US3752173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:04:16

US3752173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:04:16

US3752173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 15:26:05

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '10:10'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:10'	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:01
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:01
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:01
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:01
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:01
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '11:20' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:20'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 15:27:39
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:27:56

US3752173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:27:56

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:27:25
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 16:27:25
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:04:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '11:00' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 16:27:25
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:00'	System	18 Sep 2020 16:27:25
User entered empty.	System	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:04:34

US3752173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

US3752173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

US3752173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:25'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

US3752173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:25'	System	21 Sep 2020 15:28:21

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '10:23'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:23'	System	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:28:37

US3752173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:42

US3752173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 15:28:42

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered 'Yes (Y)'	System	18 Sep 2020 16:30:56

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:29:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered '98.0'	System	18 Sep 2020 16:30:56

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:29:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered 'No (N)'	System	18 Sep 2020 16:30:56

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered '18 Sep 2020 11:30'	System	18 Sep 2020 16:30:56

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:36:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered 'Yes (Y)'	System	19 Sep 2020 00:37:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered '97.5'	System	19 Sep 2020 00:37:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered 'No (N)'	System	19 Sep 2020 00:37:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered '18 Sep 2020 19:37'	System	19 Sep 2020 00:37:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered 'Yes (Y)'	System	21 Sep 2020 00:20:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered '99.7'	System	21 Sep 2020 00:20:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:29', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered 'No (N)'	System	21 Sep 2020 00:20:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered '19 Sep 2020 19:20'	System	21 Sep 2020 00:20:55

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:17:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered 'Yes (Y)'	System	21 Sep 2020 00:20:58

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:17:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered '98.3'	System	21 Sep 2020 00:20:58

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:00', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered 'No (N)'	System	21 Sep 2020 00:20:58

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered '20 Sep 2020 19:18'	System	21 Sep 2020 00:20:58

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'None (1)'	System	18 Sep 2020 16:32:04

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'No (N)'	System	18 Sep 2020 16:32:04

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'No (N)'	System	18 Sep 2020 16:32:04

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'None (1)'	System	18 Sep 2020 16:32:04

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered '18 Sep 2020 11:31'	System	18 Sep 2020 16:32:04

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'None (1)'	System	19 Sep 2020 00:33:40

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'No (N)'	System	19 Sep 2020 00:33:40

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'No (N)'	System	19 Sep 2020 00:33:40

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'None (1)'	System	19 Sep 2020 00:33:40

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered '18 Sep 2020 19:33'	System	19 Sep 2020 00:33:40

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'None (1)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'None (1)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered '19 Sep 2020 19:21'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'None (1)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:29', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'None (1)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered '20 Sep 2020 19:18'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5' User entered 'None (0)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'No (N)'	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:32:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5' User entered '18 Sep 2020 11:32'	System	18 Sep 2020 16:32:23
	System	18 Sep 2020 16:32:23

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:16', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda' User entered 'None (0)'	System	19 Sep 2020 00:38:41
	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'No (N)'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered '18 Sep 2020 19:38'	System	19 Sep 2020 00:38:41

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered '19 Sep 2020 19:23'	System	21 Sep 2020 00:20:56

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered '20 Sep 2020 19:19'	System	21 Sep 2020 00:20:59

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:55:21

US3752173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:55:21

US3752173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:55:31

US3752173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:55:31

US3752173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:22

US3752173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:07:22

US3752173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 16:07:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '10:35'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 10:35'	System	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '16'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '118'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 12:02:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PI reviewed vitals- no abnormalities and NCS ' (Site from System).	Haylee Rowe (b) (4)	23 Oct 2020 16:09:27
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 16:08:12
User entered '58'	Haylee Rowe (b) (4)	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 16:08:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:10:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:10:37

US3752173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

US3752173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

US3752173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:45'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

US3752173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 10:45'	System	23 Oct 2020 16:11:07

US3752173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:12

US3752173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:11:12

US3752173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'DATA ENTRY ERROR' (Site from System).	Amanda Horn (b) (4)	18 Nov 2020 16:06:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	18 Nov 2020 16:06:14
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 16:06:14
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 16:06:14
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Nov 2020 16:06:14
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	18 Nov 2020 16:06:14
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Nov 2020 16:06:14
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 16:06:14
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	12 Nov 2020 16:53:35
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	12 Nov 2020 16:53:35
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 17:27:49
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 16:06:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:28:03

US3752173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:28:03

US3752173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 20:20:49
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 20:17:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:20:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Early Termination due to death'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:22:18

US3752173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:22:18

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

[Time of Contact](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:38
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:23:27

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

[Type of Contact](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:40
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:58

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:58

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:24:16

US3752173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:47
User entered 'Yes (Y)' reason for change: New Information	Lauren Evans (b) (4)	02 Nov 2020 14:50:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:12:10

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:09
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:08:52
User entered 'USA-US113-2020-mRNA-1273-P301000007'	System	03 Nov 2020 13:08:49
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 13:08:49

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:11
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 07:11:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	04 Nov 2020 07:11:55
Data point term sent to Coder	System	02 Nov 2020 14:54:21
User entered 'Myocardial Infarction'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:14
User entered 'Yes (Y)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:16
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:19
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:23
User entered '01 Nov 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:25
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:27
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:29
User entered '01 Nov 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:32
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:35
User entered 'Grade 4 (Grade 4)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:36
User entered 'Yes (Y)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:39
User entered '1'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:40
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:42
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:44
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:47
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:49
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:51
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:52
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:58
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:01
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:03
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 15:14:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 15:14:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lauren Evans (b) (4)	02 Nov 2020 15:14:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:53:23
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:05
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 15:14:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 15:14:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lauren Evans (b) (4)	02 Nov 2020 15:14:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:53:23
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:08
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 16:56:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:56:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 14:53:23
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:14
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:16
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:17
User entered 'Fatal (FATAL)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:19
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the subject's medical circumstances prior to death.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:42
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:37
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:35
Query 'PV Query: Please provide the subject's medical circumstances prior to death.' answered with 'Coronary artery disease, COPD, hypertension, hyperlipidemia, and a previous MI in 2015.' (Site from Safety).	Haylee Rowe (b) (4)	19 Nov 2020 22:02:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment was given for this event. The patient passed away peacefully at home.' (Site from Safety).	Haylee Rowe (b) (4)	19 Nov 2020 22:01:05
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'The patient had several comorbidities that associated to this Myocardial Infarction. According to patient's PCP and Cardiologist medical records, he has coronary artery disease, COPD, hypertension, hyperlipidemia, and a previous MI in 2015.' (Site from Safety).	Haylee Rowe (b) (4)	19 Nov 2020 22:00:34

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Wife was contacted on 19 NOV 2020 and stated that no autopsy was performed. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Nov 2020 21:56:03
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:12:00
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Massive heart attack' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:06:22
User opened query 'PV Query: Please provide the subject's medical circumstances prior to death.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:15
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:01
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:10:30
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:10:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:27
User entered 'Subject's daughter called the site on 02 NOV 2020 at 8:00 and to report that the subject had died of a "massive heart attack" on 01 NOV 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:53:23

US3752173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:53:23

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:16:52

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:08:07
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 Aug 2020 10:08:07
Data point term sent to Coder	System	20 Aug 2020 20:18:49
User entered 'Fish oil'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:33
User entered 'Prophylaxis for cardiac disease'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:39
User entered '1200'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:41
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:55
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:17:51
User entered 'un May 2005'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:59
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:32:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:09:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:11
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:00
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:09:13
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		12 Nov 2020 20:07:11
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		12 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:48:05
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:17:51

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:19:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:19:21
Data point term sent to Coder	System	20 Aug 2020 20:18:50
User entered 'Omeprazole'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:03
User entered 'GERD'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:05
User entered '40'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:08
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:10
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:15
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:24
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:18:46
User entered 'un Jan 2010'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:28
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:12
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:13
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:08:50
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:08:50
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:13
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:31
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:18:46

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:42
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)	20 Aug 2020 20:20:22
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 Aug 2020 20:20:22
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	20 Aug 2020 20:19:52 20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:53:35
User entered 'Prophylaxis for cardiac disease'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:53:43
User entered '81'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:53:46
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:53:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:53:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:54:01
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:54:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:54:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:54:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:19:43
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:54:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:24
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:26
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:08:00
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:08:00
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:23
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:55:42
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:19:43

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:55:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:22:26
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 Aug 2020 20:22:26
Data point term sent to Coder	System	20 Aug 2020 20:20:59
User entered 'Carvedilol'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:11
User entered 'Hypertension'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:18
User entered '12.5'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:21
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:31
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:35
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:57:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:57:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:57:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:20:31
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:57:45
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:38
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:07:44
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:44
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:34
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:57:52
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:20:31

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:24
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)	20 Aug 2020 20:22:26
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 Aug 2020 20:22:26
Data point term sent to Coder	System	20 Aug 2020 20:22:00
User entered 'Atorvastatin'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:33
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:39
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:44
User entered '5'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:46
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:50
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:58:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:28
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:21:13
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:31
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:49
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:50
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:07:24
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:24
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:59:42
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:21:13

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:00:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:27:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:27:14
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Oct 2020 16:21:26 16 Oct 2020 16:21:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:32
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 Aug 2020 20:24:32
Data point term sent to Coder User entered 'Symbicort'	System (b) (4), (b) (6)	20 Aug 2020 20:23:02 20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:00:50
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:01:28
User entered 'Chronic obstructive pulmonary disease'	(b) (4), (b) (6)	16 Oct 2020 16:21:20
reason for change: Data Entry Error		
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:18:17
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM). DataPoint Un-verified.	Amanda Horn (b) (4)	18 Nov 2020 16:02:12
User entered '160/4.5' reason for change: Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 16:01:58
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 11:32:41
User entered '160/5'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:02:10
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:02:44
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:22:28
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:03:59
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:10:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:01
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:10:44
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:22:28

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:00
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:00
Data point term sent to Coder	System	06 Oct 2020 15:39:47
Coding entries removed.	(b) (4), (b) (6)	06 Oct 2020 15:38:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:31:17
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:31:17
Data point term sent to Coder	System	20 Aug 2020 20:24:07
User entered 'Fluticasone'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:45
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:48
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:38:49
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:05:14
User entered '50'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:39:33
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:39:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:57:59
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 17:34:56
User entered 'mg (mg)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:48:51
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:40:34
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:38:57
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:38:49
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 03:42:49
		20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:16:41
Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:39:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:39:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:39:33
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:45:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:58:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 17:34:56
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 17:34:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:06:59
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:07:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:08:33
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:08:41
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:08:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:23:36
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:10
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:11
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:49:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:13
User entered '01 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:49:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:17
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:23:36

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:26:23
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 Aug 2020 20:26:23
Data point term sent to Coder	System	20 Aug 2020 20:25:09
User entered 'Allopurinol'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:44
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:09:47
User entered 'Gout'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:04
User entered '300'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:10
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:24:25
User entered 'un Jul 2018'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:34
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:11:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:26
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:11:26
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:10:39
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:24:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:27:26
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 Aug 2020 20:27:26
Data point term sent to Coder	System	20 Aug 2020 20:26:20
User entered 'Tamsulosin'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:41
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:57
User entered 'Enlarged prostate'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:05
User entered '0.045'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:14
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:21
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:29
User entered 'unknown'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:49
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:12:59
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:25:55
User entered 'un Aug 2019'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:13:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:38
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:12:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:13:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:25:55

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:13:25
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, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:31
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Oct 2020 16:22:28 16 Oct 2020 16:21:46
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, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:28:28
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 Aug 2020 20:28:28
Data point term sent to Coder User entered 'Albuterol'	System (b) (4), (b) (6)	20 Aug 2020 20:27:22 20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:13:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:13:30
User entered 'Chronic obstructive pulmonary disease'	(b) (4), (b) (6)	16 Oct 2020 16:21:46
reason for change: Data Entry Error		
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:40:11
User entered '0.5 mg/3 mg' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:38:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:59:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:59:04
User entered '3' reason for change: Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:49:32
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:40:42
User entered '2.5' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:12:58
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:10:46
User entered '2.5/3' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:10:38
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:42:30
User entered '3'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:00
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:12:58
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:27
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:30
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:26:48
User entered 'un Jan 2020'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:10
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:12
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:12:38
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:22
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:26:48

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:30
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Oct 2020 16:22:29 16 Oct 2020 16:22:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:29
Data point term sent to Coder User entered 'Mucinex'	System (b) (4), (b) (6)	20 Aug 2020 20:28:25 20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:00
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:03
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:22:11
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:09
User entered '1200'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:10
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:23
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:27:25
User entered 'un Jan 2020'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:28
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:22
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:24
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:34
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:27:25

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:53
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)	20 Aug 2020 20:29:30
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 Aug 2020 20:29:30
Data point term sent to Coder	System	20 Aug 2020 20:28:25
User entered 'Multivitamin'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:40:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:14
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:23
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:27
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:31
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:42
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:28:04
User entered 'un Feb 2019'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:44
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:37
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:39
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:58
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:28:04

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 19:47:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	26 Oct 2020 19:47:17
Data point term sent to Coder	System	26 Oct 2020 19:34:30
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 19:34:17
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Seasonal influenza vaccine' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:40:26
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	24 Oct 2020 03:40:26
Data point term sent to Coder	System	23 Oct 2020 19:21:57
User entered 'Influenza Vaccination'	Haylee Rowe (b) (4)	23 Oct 2020 19:20:58
	(b) (4)	

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:20:11
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:20:47
User entered 'Prophylaxis for seasonal influenza' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Seasonal Flu Prevention'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:04
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered '1'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:06
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'INJ'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:10
User entered 'once (ONCE)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:11
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:14
User entered 'Intramuscular (INTRAMUSCULAR)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:17
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:20
User entered '20 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:23
User entered '0'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:26
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:33
User entered '20 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:22:39
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:20:58

US3752173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:17:37
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 19:56:52

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:21:34
User closed query 'Per CDM; please consider removing all data from this from as subject did receive second IP in Sep2020. Form will be inactivated once data is removed.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:17:38
Query 'Data is required. Please complete.' answered with 'Removed data as wrong page was opened up.' (Site from System).	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 15:33:36
Query 'Per CDM; please consider removing all data from this from as subject did receive second IP in Sep2020. Form will be inactivated once data is removed.' answered with 'Data removed.' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 15:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:58:15
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:58:15
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 14:58:15
User opened query 'Per CDM; please consider removing all data from this from as subject did receive second IP in Sep2020. Form will be inactivated once data is removed.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:21:15
User closed query 'Please complete this page in its entirety in EDC.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:10:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:36:49
Query 'Please complete this page in its entirety in EDC.' answered with 'Complete' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:02:41
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:00:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 20:00:49
User entered '01 Nov 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Nov 2020 20:00:49
User opened query 'Please complete this page in its entirety in EDC.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:03:15
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 16:52:44
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:52:44

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:51:19

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:21:37
Query 'Data is required. Please complete.' answered with 'Removed data as wrong page was opened up. ' (Site from System).	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 15:33:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:58:15
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:58:15
User entered empty; reason for change New Information	(b) (4), (b) (6)	23 Nov 2020 14:58:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:36:52
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:00:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 20:00:49
User entered 'Death (DEATH)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:00:49
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 16:52:44
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:52:44
User entered 'Death (DEATH)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:51:19

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:19:30
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:11:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:36:54
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:24:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	12 Nov 2020 20:24:34
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:23:34
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:23:34
User entered 'MYOCARDIAL INFARCTION' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:23:34
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:04:26
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:04:26
User entered 'SAE, MYOCARDIAL INFARCTION' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:04:26

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:03:15
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:03:15
User entered 'Myocardial Infarction' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:03:15
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 20:01:35
User entered 'SAE' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:01:35
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:52:44
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:52:44
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:51:51
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:51:51
User entered 'SAE' reason for change: Data Entry Error	Haylee Rowe (b) (4)	12 Nov 2020 16:51:51

US3752173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:51:19
User entered 'Subject passed away on 01 Nov 2020 due to MI.'	Haylee Rowe (b) (4)	12 Nov 2020 16:51:19

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:13
User entered '01 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:14
User entered 'Death (DEATH)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:48
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:25:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:25:31
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 14:25:11
User entered 'AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:25:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:16
User entered empty.	Haylee Rowe (b) (4)	12 Nov 2020 16:53:35

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User closed query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:20:22
User opened query 'Per CDM Re-query: Kindly enter "AE#1" in the correct field not in the query response. Kindly update CRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:20:20
Query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' answered with 'AE#1' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:01:02
User opened query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:22:14
User closed query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:57:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:17:58
Query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:09:41
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 16:09:17
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 16:08:59
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:08:59
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:08:59
User opened query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:37:27
Query 'Per CDM: per sponsor review, Death is recorded as Reason for Discontinuation, AE record number should be recorded. Please update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:36:47

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User opened query 'Per CDM: per sponsor review, Death is recorded as Reason for Discontinuation, AE record number should be recorded. Please update accordingly' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 09:59:43
	(b) (4), (b) (6)	12 Nov 2020 19:02:19
User entered 'Other (OTHER)'	Haylee Rowe (b) (4)	12 Nov 2020 16:53:35
	(b) (4)	

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:18:03
DataPoint Un-verified.	Amanda Horn (b) (4)	18 Nov 2020 16:09:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	18 Nov 2020 16:09:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:21
User entered 'MI'	Haylee Rowe (b) (4)	12 Nov 2020 16:53:35
	(b) (4)	

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:23
User entered '01 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:58

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:26
User entered 'Unknown (UNK)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:25
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'USA-US113-2020-MRNA-1273-P301000007'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:17
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:27
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:29
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:46
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:50
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Priyantha'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Wijewardane'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:59
User entered '9601 Baptist Health Drive,Suite 310'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:00
User entered 'Little Rock'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:02
User entered 'Arkansas'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:04
User entered '72022'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:07
User entered 'US'	System	03 Nov 2020 13:09:14

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 13:09:14

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:25
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'USA-US113-2020-MRNA-1273-P301000007'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:17
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:27
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:29
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:46
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:50
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Priyantha'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Wijewardane'	System	03 Nov 2020 13:08:49

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:59
User entered '9601 Baptist Health Drive,Suite 310'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:00
User entered 'Little Rock'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:02
User entered 'Arkansas'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:04
User entered '72022'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:07
User entered 'US'	System	03 Nov 2020 13:09:14

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 13:09:14

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:35
User entered '03/Nov/2020 08:09'	System	03 Nov 2020 13:09:14

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:58

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:39
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 13:09:14