

US3772051 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:16:40

All time stamps listed in this document are displayed in GMT

US3772051

Form: Participant Creation

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

[Participant ID](#)

US3772051

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

US3772051

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3772051

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3772051

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 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

US3772051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3772051

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Were any significant conditions reported?

Yes ☒

No ☐

US3772051

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3772051

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Condition	DEPRESSION
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)	_____

US3772051

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Condition	HYPERTENSION
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)	_____

US3772051

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:03 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:03
Height (<i>xxx.x</i>)	155 cm
Weight (<i>xxx.x</i>)	99.3 kg
BMI (<i>xxx.x</i>)	41.33195 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)	

US3772051

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3772051

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2000

Date of last menstruation unknown False

US3772051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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 False

Resides in Nursing Home or Assisted Living Facility False

US3772051

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 185963

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 ☒

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

Height	ND - Not Done
Weight	ND - Not Done

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

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)	12 AUG 2020
Time of assessment (00:00-23:59)	09:03 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:03
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Sep 2020 17:06:17

Generated On: 26 Nov 2020 11:16:40

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)	12 AUG 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 10:47
Temperature (xxx.x)	36.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3772051

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 10:11 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 10:11

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

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 AUG 2020

Collection time (00:00-23:59)

09:54 (24 HR)

Collection date and time (derived)

12 AUG 2020 09:54

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:57	12 AUG 2020 09:57
Nasopharyngeal Swab 2	No		

US3772051

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

12 AUG 2020 10:56

PC Open Date & Time

12 AUG 2020 10:31

PC Close Date & Time

12 AUG 2020 13:01

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐
No ☒

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

PC Time Stamp	12 AUG 2020 18:43
PC Open Date & Time	12 AUG 2020 13:56
PC Close Date & Time	13 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

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

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

13 AUG 2020 21:33

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

14 AUG 2020 19:23

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

15 AUG 2020 20:20

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:15

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

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

97.2 °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

17 AUG 2020 19:40

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:40

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 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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

12 AUG 2020 10:57

PC Open Date & Time

12 AUG 2020 10:31

PC Close Date & Time

12 AUG 2020 13:01

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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

12 AUG 2020 18:44

PC Open Date & Time

12 AUG 2020 13:56

PC Close Date & Time

13 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

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

13 AUG 2020 21:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

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

14 AUG 2020 19:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

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

15 AUG 2020 20:20

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

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

16 AUG 2020 20:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:40

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

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:40

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

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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 ☐

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 10:58
PC Open Date & Time	12 AUG 2020 10:31
PC Close Date & Time	12 AUG 2020 13:01

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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 ☐

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 18:44
PC Open Date & Time	12 AUG 2020 13:56
PC Close Date & Time	13 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

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 ☒

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

Yes ☐	
PC Time stamp	13 AUG 2020 21:34
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

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 ☒

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

Yes ☐	
PC Time stamp	14 AUG 2020 19:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

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 ☒

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

Yes ☐	
PC Time stamp	15 AUG 2020 20:21
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

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 ☒

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

Yes ☐	
PC Time stamp	16 AUG 2020 20:16
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:40

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 ☐

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:40

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 ☐

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772051

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772051

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	VISIT2

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

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.

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

WITHDRAWAL DUE TO SAE
UNRELATED TO STUDY IP OR
PROCEDURES

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:40

Collection date (*dd MMM yyyy*)

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

US3772051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3772051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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 ☐

US3772051

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3772051

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

AEID	USA-US107-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE INCARCERATED VENTRAL HERNIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	14 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

75 of 884

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

SUBJECT DID NOT SHOW UP
TODAY FOR THEIR VISIT 2,
THEIR HUSBAND INFORMED US
THAT THEY WERE
HOSPITALIZED ON 04SEP2020
DUE TO ABDOMINAL PAIN.
RECORDS WERE REQUESTED,
THIS REPORT WILL BE
UPDATED ONCE THEY ARE
RECEIVED.
ALTERNATIVE CAUSE (FROM
PI): UNKNOWN AT THIS TIME.
PENDING ARRIVAL OF
MEDICAL RECORDS. PATIENT'S
HUSBAND INDICATES BOWEL
OBSTRUCTIONS AS THE CAUSE
OF HOSPITAL ADMISSION.

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

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

AEID	
Adverse event	ACUTE KIDNEY INJURY
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)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

78 of 884

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Sep 2020 17:06:16

Generated On: 26 Nov 2020 11:16:40

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

Yes ☒

No ☐

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

Name of Medication CYCLOBENZAPRINE
HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2006
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

Name of Medication	LOTREL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	10/20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

Name of Medication	DULOXETINE EC
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	30
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 ☐

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2004
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

Name of Medication	PERCOCET
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE INCARCERATED VENTRAL HERNIA
Dose per administration	5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:40

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:16:40

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
10 SEP 2020	EXPLORATORY LAPAROTOMY WITH REPAIR OF INCARCERATED RECURRENT VENTRAL HERNIA WITH PHASIX MESH ENTERECTOMY WITH ANASTOMOSIS	Adverse Event	

US3772051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:40

Date of dosing discontinuation (dd MMM yyyy)

28 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

USA-US107-2020-MRNA-1273-P30

1000001 SAE#1

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

Date of study discontinuation/completion (dd MMM yyyy) 28 SEP 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 USA-US107-2020-MRNA-1273-P30
1000001 SAE #1

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/SEP/2020 13:28
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

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/SEP/2020 12:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/SEP/2020 10:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/SEP/2020 16:28
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

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/OCT/2020 12:49
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

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:16:40

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3772051 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772051

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:40

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'US3772051'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:49:54

US3772051

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:19:50

US3772051

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:49:55

US3772051

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:19:50

US3772051

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Aug 2020 17:19:50

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:49:56

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Age](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '67'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

Sex

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Female (F)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Ethnicity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '1'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Black](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '0'	Emily Crews (b) (4)	12 Aug 2020 17:20:21
	(b) (4)	

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[If race is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '0'	Emily Crews (b) (4)	12 Aug 2020 17:20:21
	(b) (4)	

US3772051

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:40

[Not reported](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '0'	Emily Crews (b) (4)	12 Aug 2020 17:20:21
	(b) (4)	

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Amendment 2 (2)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:49:55

US3772051

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:36:25

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 17:40:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 17:40:09
Data point term sent to Coder	System	12 Aug 2020 17:38:48
User entered 'Fibromyalgia'	(b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '2006'	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Aug 2020 17:41:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:41:11
Data point term sent to Coder	System	12 Aug 2020 17:39:50
User entered 'Depression'	(b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'un UNK 2004'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '2004'	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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.	(b) (4) Coder Import (b) (4)	12 Aug 2020 17:41:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 17:41:11
Data point term sent to Coder	System	12 Aug 2020 17:39:52
User entered 'Hypertension'	(b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'un UNK 2004'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '2004'	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Aug 2020 17:42:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:42:13
Data point term sent to Coder	System	12 Aug 2020 17:40:53
User entered 'Post Menopausal'	(b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '2000'	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '09:03'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 09:03'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '155' cm	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	
DataPoint set to visible.	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '99.3' kg	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	
DataPoint set to visible.	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
Amendment Manager: User entered '41.33195'	System	16 Sep 2020 23:53:35
User entered '41.3'	System	12 Aug 2020 17:54:32
DataPoint set to visible.	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Aug 2020 17:54:32
DataPoint set to visible.	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:40:50
User entered '36.6' C	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:40:50
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:40:50
User entered '72'	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:40:50
User entered '20'	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:40:50
User entered '125'	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:40:50
User entered '77'	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:42

US3772051

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:54:42

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '12 Aug 2020'	Emily Crews (b) (4)	12 Aug 2020 17:55:41
	(b) (4)	

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'un UNK 2000'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:41

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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 signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:40

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

US3772051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:32:02

US3772051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:32:02

US3772051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:32:02

US3772051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	12 Aug 2020 17:32:02

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:49:25

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:52:54
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:52:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:49:25
User entered '185963' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:49:25

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:49:25

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 17:45:02
User entered 'No (N)' reason for change: Data Entry Error	System	12 Aug 2020 17:45:02
User opened query 'Data is required. Please complete.' (Site from System).	Emily Crews (b) (4)	12 Aug 2020 17:45:02
User entered empty.	(b) (4)	
	System	12 Aug 2020 17:44:54
	Emily Crews (b) (4)	12 Aug 2020 17:44:54
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
Query '22Oct2020(b) (6):Per medical Hx, subject had aortic valve disease, this appeared to meet protocol examples of at risk conditions under significantt cardiac disease disease. Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 07:13:23
User opened query '22Oct2020(b) (6):Per medical Hx, subject had aortic valve disease, this appeared to meet protocol examples of at risk conditions under significantt cardiac disease disease. Please verify' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 07:12:06
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 17:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 17:45:02
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 17:45:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 17:44:54
User entered empty.	System	12 Aug 2020 17:44:54
	Emily Crews (b) (4)	12 Aug 2020 17:44:54
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:54

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 17:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 17:45:02
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 17:45:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 17:44:54
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:44:54
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

[Liver Disease](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 17:45:02
User entered 'No (N)' reason for change: Data Entry Error	System	12 Aug 2020 17:45:02
User opened query 'Data is required. Please complete.' (Site from System).	Emily Crews (b) (4)	12 Aug 2020 17:45:02
User entered empty.	(b) (4)	
	System	12 Aug 2020 17:44:54
	Emily Crews (b) (4)	12 Aug 2020 17:44:54
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 23:30:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:46:51

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '155' cm	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '99.3' kg	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '155' cm	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '99.3' kg	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '09:03'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 09:03'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '36.6' C	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '72'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '20'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '125'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '77'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '155' cm	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:40

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:41:05
User entered '99.3' kg	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered 'No (N)'	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	12 Aug 2020 18:01:28
User entered empty.	(b) (4)	
	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 06:30:57
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).	System	12 Aug 2020 18:01:28
User entered '10:47' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	12 Aug 2020 18:01:28
User entered empty.	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 10:47'	System	12 Aug 2020 18:01:28
User entered empty.	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '36.1' C reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '77' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 18:01:28
User entered empty.	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '18' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 18:01:28
User entered empty.	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '124' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 18:01:28
User entered empty.	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '88' reason for change: Data Entry Error	Emily Crews (b) (4)	12 Aug 2020 18:01:28
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:47:04
	(b) (4)	

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 18:01:28
User entered empty.	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:45:27

US3772051

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:45:27

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '10:11'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 10:11'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:45:54

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:45:54

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '09:54'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:45:54

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 09:54'	System	12 Aug 2020 17:45:54

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '12 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '09:57'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 09:57'	System	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:55:47

US3772051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:55:47

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:56:34', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'c3c7d6e4-5de2-49de-a312-de21181552d2'	System	12 Aug 2020 17:56:44
User entered 'Yes (Y)'	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:56:18', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'c3c7d6e4-5de2-49de-a312-de21181552d2'	System	12 Aug 2020 17:56:44
User entered '97.0'	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:56:24', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'c3c7d6e4-5de2-49de-a312-de21181552d2'	System	12 Aug 2020 17:56:44
User entered 'No (N)'	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:56:42', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'c3c7d6e4-5de2-49de-a312-de21181552d2'	System	12 Aug 2020 17:56:44
User entered '12 Aug 2020 10:56'	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 10:31'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:42:35', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '55ed9475-7f99-41c1-a1f2-d0eb0956a2fb'	System	13 Aug 2020 01:47:29
User entered 'Yes (Y)'	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:42:43', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '55ed9475-7f99-41c1-a1f2-d0eb0956a2fb'	System	13 Aug 2020 01:47:29
User entered '97.7'	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:42:49', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '55ed9475-7f99-41c1-a1f2-d0eb0956a2fb'	System	13 Aug 2020 01:47:29
User entered 'No (N)'	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:43:28', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '55ed9475-7f99-41c1-a1f2-d0eb0956a2fb'	System	13 Aug 2020 01:47:29
User entered '12 Aug 2020 18:43'	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:56'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 2'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:16', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7bfe5473-a085-49a1-97ec-6b8e4436c17b'	System	14 Aug 2020 04:35:22
User entered 'Yes (Y)'	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:30', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7bfe5473-a085-49a1-97ec-6b8e4436c17b'	System	14 Aug 2020 04:35:22
User entered '97.4'	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:36', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7bfe5473-a085-49a1-97ec-6b8e4436c17b'	System	14 Aug 2020 04:35:22
User entered 'No (N)'	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:40', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7bfe5473-a085-49a1-97ec-6b8e4436c17b'	System	14 Aug 2020 04:35:22
User entered '13 Aug 2020 21:33'	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 3'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:23:21', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'f7e9a9aa-05b9-4f9b-b199-d4faa6c0fb81'	System	17 Aug 2020 18:08:58
User entered 'Yes (Y)'	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:23:30', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'f7e9a9aa-05b9-4f9b-b199-d4faa6c0fb81'	System	17 Aug 2020 18:08:58
User entered '97.7'	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:23:36', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'f7e9a9aa-05b9-4f9b-b199-d4faa6c0fb81'	System	17 Aug 2020 18:08:58
User entered 'No (N)'	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:23:47', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'f7e9a9aa-05b9-4f9b-b199-d4faa6c0fb81'	System	17 Aug 2020 18:08:58
User entered '14 Aug 2020 19:23'	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 4'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:19:31', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '2ef5cb47-8363-4772-903b-7c7afbd0d40d'	System	17 Aug 2020 03:17:58
User entered 'Yes (Y)'	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:19:55', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '2ef5cb47-8363-4772-903b-7c7afbd0d40d'	System	17 Aug 2020 03:17:58
User entered '98.6'	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:02', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '2ef5cb47-8363-4772-903b-7c7afbd0d40d'	System	17 Aug 2020 03:17:58
User entered 'No (N)'	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:06', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '2ef5cb47-8363-4772-903b-7c7afbd0d40d'	System	17 Aug 2020 03:17:58
User entered '15 Aug 2020 20:20'	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 5'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:15:32', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'dcadac14-a264-4064-b3d6-956a9221a3e1'	System	17 Aug 2020 17:37:19
User entered 'Yes (Y)'	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:15:41', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'dcadac14-a264-4064-b3d6-956a9221a3e1'	System	17 Aug 2020 17:37:19
User entered '98.3'	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:15:45', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'dcadac14-a264-4064-b3d6-956a9221a3e1'	System	17 Aug 2020 17:37:19
User entered 'No (N)'	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:15:53', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'dcadac14-a264-4064-b3d6-956a9221a3e1'	System	17 Aug 2020 17:37:19
User entered '16 Aug 2020 20:15'	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 6'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-17T19:40:27', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '9094bfed-00c5-496d-b239-d36d1503c3b1'	System	18 Aug 2020 02:43:41
User entered 'Yes (Y)'	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-17T19:40:36', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '9094bfed-00c5-496d-b239-d36d1503c3b1'	System	18 Aug 2020 02:43:41
User entered '97.2'	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-17T19:40:40', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '9094bfed-00c5-496d-b239-d36d1503c3b1'	System	18 Aug 2020 02:43:41
User entered 'No (N)'	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-17T19:40:44', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '9094bfed-00c5-496d-b239-d36d1503c3b1'	System	18 Aug 2020 02:43:41
User entered '17 Aug 2020 19:40'	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 7'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:56:55', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '0f53a538-1076-4759-9c6d-1ff90ebace93'	System	12 Aug 2020 17:57:24
User entered 'None (1)'	System	12 Aug 2020 17:57:24

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:02', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '0f53a538-1076-4759-9c6d-1ff90ebace93'	System	12 Aug 2020 17:57:24
User entered 'No (N)'	System	12 Aug 2020 17:57:24

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:06', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '0f53a538-1076-4759-9c6d-1ff90ebace93'	System	12 Aug 2020 17:57:24
User entered 'No (N)'	System	12 Aug 2020 17:57:24

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:13', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '0f53a538-1076-4759-9c6d-1ff90ebace93'	System	12 Aug 2020 17:57:24
User entered 'None (1)'	System	12 Aug 2020 17:57:24

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:23', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '0f53a538-1076-4759-9c6d-1ff90ebace93'	System	12 Aug 2020 17:57:24
User entered '12 Aug 2020 10:57'	System	12 Aug 2020 17:57:24

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 10:31'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:43:58', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'd9acd220-4c59-47a2-85a6-1cfb4c0ee382'	System	13 Aug 2020 01:47:34
User entered 'None (1)'	System	13 Aug 2020 01:47:34

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:04', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'd9acd220-4c59-47a2-85a6-1cfb4c0ee382'	System	13 Aug 2020 01:47:34
User entered 'No (N)'	System	13 Aug 2020 01:47:34

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:11', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'd9acd220-4c59-47a2-85a6-1cfb4c0ee382'	System	13 Aug 2020 01:47:34
User entered 'No (N)'	System	13 Aug 2020 01:47:34

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:14', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'd9acd220-4c59-47a2-85a6-1cfb4c0ee382'	System	13 Aug 2020 01:47:34
User entered 'None (1)'	System	13 Aug 2020 01:47:34

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:18', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'd9acd220-4c59-47a2-85a6-1cfb4c0ee382'	System	13 Aug 2020 01:47:34
User entered '12 Aug 2020 18:44'	System	13 Aug 2020 01:47:34

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:56'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 2'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:50', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7969a208-7ece-4ea0-9b88-0d9f45a81833'	System	14 Aug 2020 04:35:27
User entered 'None (1)'	System	14 Aug 2020 04:35:27

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:33:55', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7969a208-7ece-4ea0-9b88-0d9f45a81833'	System	14 Aug 2020 04:35:27
User entered 'No (N)'	System	14 Aug 2020 04:35:27

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:03', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7969a208-7ece-4ea0-9b88-0d9f45a81833'	System	14 Aug 2020 04:35:27
User entered 'No (N)'	System	14 Aug 2020 04:35:27

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:09', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7969a208-7ece-4ea0-9b88-0d9f45a81833'	System	14 Aug 2020 04:35:27
User entered 'None (1)'	System	14 Aug 2020 04:35:27

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:18', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '7969a208-7ece-4ea0-9b88-0d9f45a81833'	System	14 Aug 2020 04:35:27
User entered '13 Aug 2020 21:34'	System	14 Aug 2020 04:35:27

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 3'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:24:07', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cedc5fbe-cbba-4614-bd1e-278735fa1318'	System	17 Aug 2020 17:37:02
User entered 'None (1)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:24:11', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cedc5fbe-cbba-4614-bd1e-278735fa1318'	System	17 Aug 2020 17:37:02
User entered 'No (N)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:24:16', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cedc5fbe-cbba-4614-bd1e-278735fa1318'	System	17 Aug 2020 17:37:02
User entered 'No (N)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:24:25', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cedc5fbe-cbba-4614-bd1e-278735fa1318'	System	17 Aug 2020 17:37:02
User entered 'None (1)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:24:45', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cedc5fbe-cbba-4614-bd1e-278735fa1318'	System	17 Aug 2020 17:37:02
User entered '14 Aug 2020 19:24'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 4'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:13', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a6223fa2-0ee5-4955-921a-b7146c9cee9b'	System	17 Aug 2020 03:18:07
User entered 'None (1)'	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:17', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a6223fa2-0ee5-4955-921a-b7146c9cee9b'	System	17 Aug 2020 03:18:07
User entered 'No (N)'	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:19', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a6223fa2-0ee5-4955-921a-b7146c9cee9b'	System	17 Aug 2020 03:18:07
User entered 'No (N)'	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:24', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a6223fa2-0ee5-4955-921a-b7146c9cee9b'	System	17 Aug 2020 03:18:07
User entered 'None (1)'	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:41', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a6223fa2-0ee5-4955-921a-b7146c9cee9b'	System	17 Aug 2020 03:18:07
User entered '15 Aug 2020 20:20'	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 5'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:00', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'b5fcc7d0-642b-4303-b27a-aac4709b09d3'	System	17 Aug 2020 17:37:29
User entered 'None (1)'	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:04', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'b5fcc7d0-642b-4303-b27a-aac4709b09d3'	System	17 Aug 2020 17:37:29
User entered 'No (N)'	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:06', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'b5fcc7d0-642b-4303-b27a-aac4709b09d3'	System	17 Aug 2020 17:37:29
User entered 'No (N)'	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:08', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'b5fcc7d0-642b-4303-b27a-aac4709b09d3'	System	17 Aug 2020 17:37:29
User entered 'None (1)'	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:11', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'b5fcc7d0-642b-4303-b27a-aac4709b09d3'	System	17 Aug 2020 17:37:29
User entered '16 Aug 2020 20:16'	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 6'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 7'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:31', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:41', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:46', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:50', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:54', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:57:57', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'None (0)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:58:04', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered 'No (N)'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T10:58:09', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ce8604aa-010a-4075-8fb0-b0d50aedb125'	System	12 Aug 2020 17:58:11
User entered '12 Aug 2020 10:58'	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 10:31'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:25', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:28', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:33', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:38', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:42', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:45', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'None (0)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:52', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered 'No (N)'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-12T18:44:57', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: '771a2953-a1f7-467c-8e0f-4cf3060c69d5'	System	13 Aug 2020 01:47:35
User entered '12 Aug 2020 18:44'	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:56'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 2'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:28', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:31', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:36', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:39', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:44', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:47', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'None (0)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:54', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered 'No (N)'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-13T21:34:58', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'bfe36ede-5d24-455d-b119-a7503fa08ecc'	System	14 Aug 2020 04:35:28
User entered '13 Aug 2020 21:34'	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 3'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:01', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:06', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:13', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:18', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:21', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:24', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'None (0)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:31', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered 'No (N)'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-14T19:25:38', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'a2c58d05-aba1-494f-8986-75369c2fe874'	System	17 Aug 2020 17:37:02
User entered '14 Aug 2020 19:25'	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 4'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:54', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d' User entered 'None (0)'	System	17 Aug 2020 03:18:13
	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:20:59', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d' User entered 'None (0)'	System	17 Aug 2020 03:18:13
	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:03', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d'	System	17 Aug 2020 03:18:13
User entered 'None (0)'	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:07', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d' User entered 'None (0)'	System	17 Aug 2020 03:18:13
	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:12', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d'	System	17 Aug 2020 03:18:13
User entered 'None (0)'	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:14', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d'	System	17 Aug 2020 03:18:13
User entered 'None (0)'	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:18', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d'	System	17 Aug 2020 03:18:13
User entered 'No (N)'	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-15T20:21:23', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'ab3c13bb-2e56-4996-ae50-21ea8878954d'	System	17 Aug 2020 03:18:13
User entered '15 Aug 2020 20:21'	System	17 Aug 2020 03:18:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 5'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:17', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'None (0)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:20', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'None (0)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:25', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'None (0)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:29', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e' User entered 'None (0)'	System	17 Aug 2020 17:39:09
	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:31', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'None (0)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:34', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'None (0)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

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 (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:39', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered 'No (N)'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8D73FE52-86E9-430F-B25E-000DEFA49C2D)', Time: '2020-08-16T20:16:42', User OID: 'PatientReportedOutcome (US3772051)', ODM File OID: 'cdbfebdd-1a1f-4522-821e-cde26b04c21e'	System	17 Aug 2020 17:39:09
User entered '16 Aug 2020 20:16'	System	17 Aug 2020 17:39:09

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 6'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:44:13
User entered 'Day 7'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:44:13

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:44:13

US3772051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:34

US3772051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Protocol deviation '11Sep2020(b) (6):Safety call day 8 is 4 days OOW. Please reconcile.' inactivated.	(b) (4), (b) (6)	19 Sep 2020 06:09:02
User closed query '11Sep2020(b) (6): Please confirm as safety call day 8 and day 15 have the same date. Please update and correct.' (Site from CRA).	(b) (4), (b) (6)	19 Sep 2020 06:07:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Query '11Sep2020(b) (6): Please confirm as safety call day 8 and day 15 have the same date. Please update and correct.' answered with 'Transcription error' (Site from CRA).	Emily Crews (b) (4)	15 Sep 2020 23:40:20
User closed query 'Safety Call Day 8 'Date of ContactSystem or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		15 Sep 2020 23:40:10
Query 'Safety Call Day 8 'Date of Contact or Contact System Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		15 Sep 2020 23:40:10
User entered '20 Aug 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 23:40:10
User opened query '11Sep2020(b) (6): Please confirm as safety call day 8 and day 15 have the same date. Please update and correct.' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 04:11:20
Protocol deviation created: 11Sep2020(b) (6):Safety call day 8 is 4 days OOW. Please reconcile. Class: Non-compliance with visit schedule Code: Deviation.	(b) (4), (b) (6)	12 Sep 2020 04:08:54
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Aug 2020 21:53:34
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:53:34

US3772051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:34

US3772051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:34

US3772051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:43

US3772051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 21:53:43

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:54

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:54

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:54

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:54

US3772051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:53:59

US3772051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 21:53:59

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '02 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:25:08

US3772051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 20:25:08

US3772051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Oct 2020 17:00:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:01

US3772051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:01

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'Withdrawal due to SAE unrelated to study IP or procedures'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:01:53

US3772051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:02:00

US3772051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:02:00

US3772051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:41:26

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 19:27:00
Un-reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 19:26:52
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:50:48
User entered 'USA-US107-2020-mRNA-1273-P301000001'	System	15 Sep 2020 14:50:40
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 14:50:40

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Incarcerated hernia, LLT: Incarcerated hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:15:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:15:44
Data point term sent to Coder	System	17 Sep 2020 20:26:12
Coding entries removed.	(b) (4), (b) (6)	17 Sep 2020 20:25:56
Signature has been broken.	(b) (4), (b) (6)	17 Sep 2020 20:25:56
User entered 'Acute incarcerated ventral hernia' reason for change: New Information	(b) (4), (b) (6)	17 Sep 2020 20:25:56
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:55:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:55:53
Data point term sent to Coder	System	14 Sep 2020 17:54:30
User entered 'Abdominal Pain'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:48:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'this is an ongoing the subject has dropped out of the study ' (Site from Safety).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:16:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:55:40
User entered empty.	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query '28Oct2020(b) (6):Per medical records, subject was discharged on 14Sep2020. Kindly update and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:13:22
Query '28Oct2020(b) (6):Per medical records, subject was discharged on 14Sep2020. Kindly update and correct.' answered with 'Discharge date is mentioned below, please clarify.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:57:04
Query '28Oct2020(b) (6): Per medical records, subject was admitted 04Sep2020. Please reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 06:35:45
User opened query '28Oct2020(b) (6): Per medical records, subject was admitted 04Sep2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 06:34:19
User opened query '28Oct2020(b) (6):Per medical records, subject was discharged on 14Sep2020. Kindly update and correct.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 06:32:01
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 13:22:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'The discharge date is unknown at this time' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:00:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:54:00
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify the hospital admission date. Per discharge summary, the admit date was 05 Sep 2020 rather than 04 Sep 2020. Please updated as applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:48:43
Query 'PV Query: Please clarify the hospital admission date. Per discharge summary, the admit date was 05 Sep 2020 rather than 04 Sep 2020. Please updated as applicable.' answered with 'updated, Subject was seen in emergency room on 04 Sep 2020 and admitted on 05 Sep 2020' (Site from Safety). Signature has been broken.	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:17:36
User entered '05 Sep 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:17:14
User opened query 'PV Query: Please clarify the hospital admission date. Per discharge summary, the admit date was 05 Sep 2020 rather than 04 Sep 2020. Please updated as applicable.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Jamshid Saleh (b) (4) (b) (4)	08 Oct 2020 13:05:03
User entered '04 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:06:17
		14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:34:22
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM Re-query: As per CCGs, p. 35, If Investigational product was permanently discontinued due to this adverse event then Investigational Product Withdrawn must be selected. Kindly review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 22:24:06
User closed query 'PV Query: Please confirm action taken with the study drug. Was the study drug withdrawn due to the SAE of "Acute Incarcerated Ventral Hernia", if so please consider updating action taken.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:25:40
Query 'PV Query: Please confirm action taken with the study drug. Was the study drug withdrawn due to the SAE of "Acute Incarcerated Ventral Hernia", if so please consider updating action taken.' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4)	19 Oct 2020 17:07:41
Query 'Per CDM Re-query: As per CCGs, p. 35, If Investigational product was permanently discontinued due to this adverse event then Investigational Product Withdrawn must be selected. Kindly review and reconcile, else clarify. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4)	19 Oct 2020 17:07:36
Signature has been broken.	Emily Crews (b) (4)	19 Oct 2020 17:07:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Emily Crews (b) (4)	19 Oct 2020 17:07:26
User opened query 'PV Query: Please confirm action taken with the study drug. Was the study drug withdrawn due to the SAE of "Acute Incarcerated Ventral Hernia", if so please consider updating action taken.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:55:33
User opened query 'Per CDM Re-query: As per CCGs, p. 35, If Investigational product was permanently discontinued due to this adverse event then Investigational Product Withdrawn must be selected. Kindly review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 08:58:58
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	14 Sep 2020 23:01:10
reason for change: Data Entry Error		
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

None

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	24 Sep 2020 16:25:11
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:25:11
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:27:02
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Conmeds will be updated after receipt of Medical Records' (Site from DM).	Emily Crews (b) (4) (b) (4)	23 Sep 2020 23:51:10
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:29:58
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:06:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Sep 2020 23:01:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 23:01:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Sep 2020 17:54:00
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	24 Sep 2020 16:25:11
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Sep 2020 16:25:11
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	24 Sep 2020 16:38:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Sep 2020 16:38:23
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:48:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'subject has not recovered and has dropped out of the study' (Site from Safety).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:16:38
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:04:44
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject has withdrawn consent due to this SAE. They have not recovered or resolved as of Term Date' (Site from Safety).	Emily Crews (b) (4) (b) (4)	29 Sep 2020 22:22:43
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:56:37
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol if subject desires to withdraw from the study due to a SAE, the site will try to obtain agreement to follow up with the subject until event resolution. Please confirm if follow up is expected to obtain outcome? If so provide event outcome and event stop date.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 19:29:36
Query 'PV Query: Per protocol if subject desires to withdraw from the study due to a SAE, the site will try to obtain agreement to follow up with the subject until event resolution. Please confirm if follow up is expected to obtain outcome? If so provide event outcome and event stop date.' answered with 'The subject did not give the site permission to obtain the outcome of this SAE.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:20:20
User closed query 'PV Query: Please confirm if the SAE of "Acute Incarcerated Ventral Hernia" was the reason for discontinuation, withdrawal of consent by participant.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:25:57
Query 'PV Query: Please confirm if the SAE of "Acute Incarcerated Ventral Hernia" was the reason for discontinuation, withdrawal of consent by participant.' answered with 'Subject withdrew consent to focus on healing from this SAE' (Site from Safety).	Emily Crews (b) (4) (b) (4)	19 Oct 2020 17:07:09
User opened query 'PV Query: Per protocol if subject desires to withdraw from the study due to a SAE, the site will try to obtain agreement to follow up with the subject until event resolution. Please confirm if follow up is expected to obtain outcome? If so provide event outcome and event stop date.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:58:50
User opened query 'PV Query: Please confirm if the SAE of "Acute Incarcerated Ventral Hernia" was the reason for discontinuation, withdrawal of consent by participant.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:57:45
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:19

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Narrative](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:16
Query 'PV Query: Please report if the patient had any history of abdominal surgery, trauma, medical history or other risk factors that would predispose to a ventral hernia.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:13
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 16:27:07
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Redacted Discharge Summary has been faxed to listed fax number' (Site from Safety).	Emily Crews (b) (4)	29 Sep 2020 22:53:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No Covid-19 testing performed during hospital admission' (Site from Safety).	Emily Crews (b) (4)	29 Sep 2020 22:34:46
User opened query 'PV Query: Please report if the patient had any history of abdominal surgery, trauma, medical history or other risk factors that would predispose to a ventral hernia.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:57:26

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:57:18
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)	24 Sep 2020 17:56:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:55:58
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 17:55:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'SUBJECT DID NOT SHOW UP TODAY FOR THEIR VISIT 2, THEIR HUSBAND INFORMED US THAT THEY WERE HOSPITALIZED ON 04SEP2020 DUE TO ABDOMINAL PAIN. RECORDS WERE REQUESTED, THIS REPORT WILL BE UPDATED ONCE THEY ARE RECEIVED.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:03:29
Alternative cause (From PI): Unknown at this time. Pending arrival of medical records. Patient's husband indicates Bowel Obstructions as the cause of hospital admission.' reason for change: Data Entry Error		
User entered 'Subject did not show up today for their visit 2, their husband informed us that they were hospitalized on 04Sep2020 due to Abdominal Pain. Records were requested, this report will be updated once they are received.'	(b) (4), (b) (6)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:30:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:30:43
Data point term sent to Coder	System	17 Sep 2020 20:28:18
User entered 'Acute Kidney Injury'	(b) (4), (b) (6) (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '05 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 20:27:54

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:48:36

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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)	12 Aug 2020 17:51:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 17:51:14
Data point term sent to Coder	System	12 Aug 2020 17:50:16
User entered 'Aspirin'	Emily Crews (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Cardiac Prophylaxis'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '81'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:35:40
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	12 Aug 2020 17:50:13
User entered 'un UNK 2000'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:50:13

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 22:41:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:41:11
Data point term sent to Coder	System	12 Aug 2020 17:52:19
User entered 'Cyclobenzaprine Hydrochloride'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Fibromyalgia'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '20'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:35:45
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	12 Aug 2020 17:51:19
User entered 'un UNK 2006'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE, PRODUCTSYNONYM: LOTREL [AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 10:14:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 10:14:04
Data point term sent to Coder	System	12 Aug 2020 17:53:22
User entered 'Lotrel'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Hypertension'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '10/20'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:35:52
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	12 Aug 2020 17:52:34
User entered 'un UNK 2004'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 00:07:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:07:19
Data point term sent to Coder	System	12 Aug 2020 17:53:20
User entered 'Duloxetine EC'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Depression'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '30'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'twice daily (BID)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:35:57
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	12 Aug 2020 17:53:19
User entered 'un UNK 2004'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
Query '23Oct2020(b) (6): Source is not marked if ongoing or stopped. Please update and correct.' answered with 'Updated source appropriately ' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 16:23:09
User opened query '23Oct2020(b) (6): Source is not marked if ongoing or stopped. Please update and correct.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 22:40:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:53:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:29:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:29:38
Data point term sent to Coder	System	24 Sep 2020 16:26:12
User entered 'Percocet'	(b) (4), (b) (6) (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Acute incarcerated ventral Hernia'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/325'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:39:08

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:16:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:16:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Exploratory Laparotomy with repair of incarcerated recurrent ventral hernia with Phasix mesh Enterectomy with anastomosis'	(b) (4), (b) (6)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:16:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:16:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:40:11

US3772051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:40

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 23:29:25

US3772051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:40

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'SAE (specify) (SAE)'	(b) (4), (b) (6)	28 Sep 2020 23:29:25

US3772051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' answered with 'updated' (Site from DM).	Emily Crews (b) (4)	24 Nov 2020 17:44:35
User entered 'USA-US107-2020-MRNA-1273-P301000001 SAE#1' reason for change: Data Entry Error	Emily Crews (b) (4)	24 Nov 2020 17:44:31
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:52:53
User closed query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:29:10
Query 'Per CDM: Please record SAE record number instead of details ' answered with 'updated' (Site from DM).	Emily Crews (b) (4)	18 Nov 2020 23:38:19
User entered 'USA-US107-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Emily Crews (b) (4)	18 Nov 2020 23:38:14
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:50:20
User entered 'Acute incarcerated ventral hernia'	(b) (4), (b) (6)	28 Sep 2020 23:29:25

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears IP discontinuation is for an SAE yet it is recorded here as Withdrawal of Consent. Please review and reconcile as these should be the same since the dates are the same. If truly SAE, also record SAE record number in the appropriate data field.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:29:22
Query 'Per CDM: it appears IP discontinuation is for an SAE yet it is recorded here as Withdrawal of Consent. Please review and reconcile as these should be the same since the dates are the same. If truly SAE, also record SAE record number in the appropriate data field.' answered with 'updated' (Site from DM).	Emily Crews (b) (4)	18 Nov 2020 23:38:45
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 23:38:39
User opened query 'Per CDM: it appears IP discontinuation is for an SAE yet it is recorded here as Withdrawal of Consent. Please review and reconcile as these should be the same since the dates are the same. If truly SAE, also record SAE record number in the appropriate data field.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:52:27
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 17:45:04
User entered 'USA-US107-2020-MRNA-1273-P301000001 SAE #1' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 17:44:58
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 01:53:03
User entered 'USA-US107-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:38:39
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	28 Sep 2020 23:30:10
User entered 'SAE' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	28 Sep 2020 23:30:10
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	28 Sep 2020 23:29:55
User entered empty.	(b) (4), (b) (6) (b) (4)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:40

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 23:29:55

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '15/Sep/2020 10:51'	(b) (4) System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '15/Sep/2020 13:28'	(b) (4) System	15 Sep 2020 17:28:41

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:28:41

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Sep/2020 12:01'	System	18 Sep 2020 16:01:20

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
User entered '1'	(b) (4), (b) (6)	18 Sep 2020 16:01:20

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '25/Sep/2020 10:55'	System	25 Sep 2020 14:55:26

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 16:27:48
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:55:26

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '30/Sep/2020 16:28'	System	30 Sep 2020 16:28:02

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:48:55
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 16:28:02

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '08/Oct/2020 12:49'	System	08 Oct 2020 16:49:05

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:26:13
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 16:49:05

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'USA-US107-2020-MRNA-1273-P301000001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Yes (Y)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'No (N)'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Jamshid'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Saleh'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '3652 Eureka Way'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered 'Redding'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
Un-reviewed for Safety.	System	18 Sep 2020 16:01:20
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered empty.	System	18 Sep 2020 16:01:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered 'California'	(b) (4), (b) (6)	15 Sep 2020 22:19:13

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:51:12
User entered '96001'	System	15 Sep 2020 14:50:40

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[Investigator Country](#)

Audit	User	Time (GMT)
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:46:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:28:26
User entered 'US' (non-conformant).	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	20 Oct 2020 14:26:27
User entered '6'	System	08 Oct 2020 16:49:05
User entered '5'	System	30 Sep 2020 16:28:02
User entered '4'	System	25 Sep 2020 14:55:26
Signature has been broken.	System	18 Sep 2020 16:01:20
User entered '3'	System	18 Sep 2020 16:01:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '2'	System	15 Sep 2020 17:28:41
User entered '1'	System	15 Sep 2020 14:51:19

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:16:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Oct/2020 14:26'	System	20 Oct 2020 14:26:27

US3772051

Folder: SAE USA-US107-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:16:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 14:26:27