

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

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:40:55

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US3772051

Form: Participant Creation

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

Generated On: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3772051

Folder: Screening

Form: Demographics

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

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
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

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Folder: Screening

Form: Enrollment

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

Generated On: 10 Jun 2021 09:40:55

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 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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: 10 Jun 2021 09:40:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

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

Generated On: 10 Jun 2021 09:40:55

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:00:32

Generated On: 10 Jun 2021 09:40:55

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:00:32

Generated On: 10 Jun 2021 09:40:55

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 22:00:32

Generated On: 10 Jun 2021 09:40:55

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 22:00:32

Generated On: 10 Jun 2021 09:40:55

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 22:00:32

Generated On: 10 Jun 2021 09:40:55

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

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

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

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Folder: Screening

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:40:55

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.

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Folder: Screening

Form: Childbearing Potential

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

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Screening

Form: Risk of Exposure

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

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Screening

Form: Risk of Exposure

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

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

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

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

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Folder: Visit 1 Day 1

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:40:55

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.

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Folder: Visit 1 Day 1

Form: Exposure

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

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

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

Generated On: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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		

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Folder: Visit 1 Day 1

Form: Continuing

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

Generated On: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:40:55

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 ☒

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EAB) (1725)

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US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

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: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

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

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

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

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

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

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

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

Data signed: (b) (4) 16 Feb 2021 20:37:50

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3772051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:40:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3772051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

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

Generated On: 10 Jun 2021 09:40:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3772051

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

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

Generated On: 10 Jun 2021 09:40:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3772051

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

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

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 _____

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

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

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

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

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3772051

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3772051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

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Folder: Adverse Events

Form: Adverse Events Summary

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

Generated On: 10 Jun 2021 09:40:55

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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

AEID	USA-US107-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE INCARCERATED VENTRAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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: 10 Jun 2021 09:40:55

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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

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

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (dd MMM yyyy)	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

Data signed: (b) (4) 13 Mar 2021 00:21:08

Generated On: 10 Jun 2021 09:40:55

Date of dosing discontinuation (dd MMM yyyy) 28 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE#1

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 13 Mar 2021 00:21:08

Generated On: 10 Jun 2021 09:40:55

Date of study discontinuation/completion (dd MMM yyyy) 28 SEP 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #1

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3772051

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

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 19 Feb 2021 22:00:31

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US107-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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: 10 Jun 2021 09:40:55

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

Form: Participant Creation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44

US3772051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Clinic (Clinic)'	Emily Crews (b) (4)	12 Aug 2020 17:19:50

US3772051

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'SCRN'	System	12 Aug 2020 17:19:50

US3772051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'YEARS'	System	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '67'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:20:21

US3772051

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: Enrollment

Generated On: 10 Jun 2021 09:40:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Aug 2020'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2020'	System	12 Aug 2020 17:20:50

US3772051

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:40:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'I'	System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Jan 2006'	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2006'	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:38:46

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	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 17:39:50
User entered 'Depression'	(b) (4), (b) (6)	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Jan 2004'	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2004'	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:06

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (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 17:39:52
User entered 'Hypertension'	(b) (4), (b) (6)	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Jan 2004'	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2004'	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:29

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	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)	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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Jan 2000'	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2000'	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	12 Aug 2020 17:39:54

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 22:58:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 22:58:29
Data point term sent to Coder	System	30 Dec 2020 22:57:53
User entered 'Obesity'	Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'UN UNK 2005'	(b) (4) Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'Jan 2005'	System	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '2005'	System	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	30 Dec 2020 22:57:51

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '12 Aug 2020 09:03'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '155' cm	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '99.3' kg	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:54:32
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:32:14

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 '36.6' C	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 '72'	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'bpm'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'breaths/min'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 '125'	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'mmHg'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 '77'	Emily Crews (b) (4)	12 Aug 2020 17:54:32
	(b) (4)	

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'mmHg'	System	12 Aug 2020 17:54:32

US3772051

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44

US3772051

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 17:55:41

US3772051

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:40:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'VISIT1'	System	12 Aug 2020 17:32:02

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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)	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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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)	

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.		09 Apr 2021 00:13:54
Data hard locked.		03 Apr 2021 09:24:12
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).		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) 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) (b) (4)	12 Aug 2020 17:45:02
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) (b) (4)	12 Aug 2020 17:44:54

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.		09 Apr 2021 00:13:54
Data hard locked.		03 Apr 2021 09:24:12
User closed query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' (Site from DM).		31 Dec 2020 16:56:40
Query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' answered with 'This subject W/C from the study therefore the start date of this condition can not be obtained.' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	23 Dec 2020 23:26:20
User opened query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:50:44
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	12 Aug 2020 17:44:54

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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) 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) (b) (4)	12 Aug 2020 17:45:02
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) (b) (4)	12 Aug 2020 17:44:54

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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) 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) (b) (4)	12 Aug 2020 17:45:02
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) (b) (4)	12 Aug 2020 17:44:54

US3772051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:30:39
Amendment Manager: DataPoint set to visible.	(b) (4) 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: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'bpm'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'breaths/min'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'mmHg'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'mmHg'	System	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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	Emily Crews (b) (4)	12 Aug 2020 17:47:04

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	12 Aug 2020 18:01:28
User entered 'No (N)'	(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: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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 System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '36.1' C 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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Oral (Oral)' 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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '77' 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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '18' 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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '124' 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

US3772051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '88' 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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	Emily Crews (b) (4)	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered '12 Aug 2020 10:11'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'ONCE'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:44:13

US3772051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered empty.	System	12 Aug 2020 17:46:09

US3772051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:14:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'l'	System	12 Aug 2020 17:55:47

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	12 Aug 2020 17:56:44
	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '97.0'	System	12 Aug 2020 17:56:44
	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '12 Aug 2020 10:56'	System	12 Aug 2020 17:56:44
	System	12 Aug 2020 17:56:44

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	13 Aug 2020 01:47:29
	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '97.7'	System	13 Aug 2020 01:47:29
	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	13 Aug 2020 01:47:29
	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '12 Aug 2020 18:43'	System	13 Aug 2020 01:47:29
	System	13 Aug 2020 01:47:29

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	14 Aug 2020 04:35:22
	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '97.4'	System	14 Aug 2020 04:35:22
	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '13 Aug 2020 21:33'	System	14 Aug 2020 04:35:22
	System	14 Aug 2020 04:35:22

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	17 Aug 2020 18:08:58
	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '97.7'	System	17 Aug 2020 18:08:58
	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '14 Aug 2020 19:23'	System	17 Aug 2020 18:08:58
	System	17 Aug 2020 18:08:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	17 Aug 2020 03:17:58
	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '98.6'	System	17 Aug 2020 03:17:58
	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 03:17:58
	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '15 Aug 2020 20:20'	System	17 Aug 2020 03:17:58
	System	17 Aug 2020 03:17:58

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	17 Aug 2020 17:37:19
	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '98.3'	System	17 Aug 2020 17:37:19
	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 17:37:19
	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '16 Aug 2020 20:15'	System	17 Aug 2020 17:37:19
	System	17 Aug 2020 17:37:19

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'Yes (Y)'	System	18 Aug 2020 02:43:41
	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '97.2'	System	18 Aug 2020 02:43:41
	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	18 Aug 2020 02:43:41
	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '17 Aug 2020 19:40'	System	18 Aug 2020 02:43:41
	System	18 Aug 2020 02:43:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (1)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '14 Aug 2020 19:24'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (1)'	System	17 Aug 2020 03:18:07
	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 03:18:07
	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 03:18:07
	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (1)'	System	17 Aug 2020 03:18:07
	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '15 Aug 2020 20:20'	System	17 Aug 2020 03:18:07
	System	17 Aug 2020 03:18:07

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (1)'	System	17 Aug 2020 17:37:29
	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 17:37:29
	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 17:37:29
	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (1)'	System	17 Aug 2020 17:37:29
	System	17 Aug 2020 17:37:29

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '12 Aug 2020 10:58'	System	12 Aug 2020 17:58:11
	System	12 Aug 2020 17:58:11

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	13 Aug 2020 01:47:35
	System	13 Aug 2020 01:47:35

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '13 Aug 2020 21:34'	System	14 Aug 2020 04:35:28
	System	14 Aug 2020 04:35:28

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'None (0)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '14 Aug 2020 19:25'	System	17 Aug 2020 17:37:02
	System	17 Aug 2020 17:37:02

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	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: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '15 Aug 2020 20:21'	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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered 'No (N)'	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: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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' User entered '16 Aug 2020 20:16'	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: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41

US3772051

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:15:41
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: 10 Jun 2021 09:40:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:14
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:14
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'l'	System	26 Aug 2020 21:53:43

US3772051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
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: 10 Jun 2021 09:40:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 00:13:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:24:12
User entered 'l'	System	26 Aug 2020 21:53:59

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered '02 Sep 2020'	Sarah Sandberg (b) (4)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:25:04

US3772051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:25:08

US3772051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'I'	System	17 Sep 2020 20:25:08

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:00:56

US3772051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:01

US3772051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:01

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'Withdrawal due to SAE unrelated to study IP or procedures'	Emily Crews (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:40

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:47

US3772051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered empty.	(b) (4) 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: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:01:53

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:50
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 17:02:00

US3772051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	15 Oct 2020 17:02:00

US3772051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:41:26

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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)	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)	17 Sep 2020 22:15:44
Data point term sent to Coder	System	17 Sep 2020 20:26:12
Coding entries removed.	Sarah Sandberg (b) (4)	17 Sep 2020 20:25:56
Signature has been broken.	(b) (4)	
	Sarah Sandberg (b) (4)	17 Sep 2020 20:25:56
User entered 'Acute incarcerated ventral hernia' reason for change: New Information	(b) (4)	
User signature succeeded.	Sarah Sandberg (b) (4)	17 Sep 2020 20:25:56
	Jamshid Saleh (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.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (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'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '04 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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) (b) (4)	16 Sep 2020 17:06:17
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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).	Sarah Sandberg (b) (4)	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 'I'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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) (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).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:17:36
Signature has been broken.	Emily Crews (b) (4) (b) (4)	08 Oct 2020 15:17:14
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).	(b) (4), (b) (6)	08 Oct 2020 13:05:03
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:06:17
User entered '04 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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)	
	Sarah Sandberg (b) (4)	15 Sep 2020 15:34:22
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

US3772051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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) (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) (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) (b) (4)	19 Oct 2020 17:07:36
Signature has been broken.	Emily Crews (b) (4) (b) (4)	19 Oct 2020 17:07:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Emily Crews (b) (4) (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

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[Action taken with investigational product](#)

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

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Signature has been broken.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:11
User entered '0' reason for change: Data Entry Error	(b) (4) Sarah Sandberg (b) (4)	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) (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	Sarah Sandberg (b) (4) (b) (4)	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'	Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Signature has been broken.	(b) (4)	
	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:11
	(b) (4)	
User entered '1' reason for change: New Information	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:11
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00
	(b) (4)	

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Signature has been broken.	(b) (4)	
	Sarah Sandberg (b) (4)	24 Sep 2020 16:38:23
	(b) (4)	
User entered '1' reason for change: New Information	Sarah Sandberg (b) (4)	24 Sep 2020 16:38:23
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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)	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)'	Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	14 Sep 2020 17:54:00

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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).	Sarah Sandberg (b) (4) (b) (4)	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

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Folder: Adverse Events

Form: Adverse Events (1)

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[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

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[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.	Sarah Sandberg (b) (4)	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.'	Sarah Sandberg (b) (4)	14 Sep 2020 17:54:00

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'I'	System	14 Sep 2020 17:54:00

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'I'	System	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '0'	System	14 Sep 2020 17:54:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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.	(b) (4) Coder Import (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)	17 Sep 2020 20:30:43
Data point term sent to Coder	System	17 Sep 2020 20:28:18
User entered 'Acute Kidney Injury'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54
	(b) (4)	

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '05 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	17 Sep 2020 20:27:54

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '14 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered empty.	System	17 Sep 2020 20:27:54

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Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Dose Delayed (DOSE DELAYED)'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'I'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '0'	System	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered 'I'	System	17 Sep 2020 20:27:54

US3772051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:40:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 User entered 'Aspirin'	System Emily Crews (b) (4)	12 Aug 2020 17:50:16 12 Aug 2020 17:50:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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) (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)	12 Aug 2020 17:50:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '1'	System	12 Aug 2020 17:50:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '1'	System	12 Aug 2020 17:50:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '804 (804)'	System	12 Aug 2020 17:50:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:06:17
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4)	12 Aug 2020 17:51:19

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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.	Coder Import (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)	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)	12 Aug 2020 17:52:34

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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) (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: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User closed query '23Oct2020(b) (6): Source is not marked if ongoing or stopped. Please update and correct.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 19:54:46
Query '23Oct2020(b) (6): Source is not marked if ongoing or stopped. Please update and correct.' answered with 'Updated source appropriately ' (Site from CRA).	Sarah Sandberg (b) (4) (b) (4)	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) (b) (4)	16 Sep 2020 17:06:17
User entered 'Yes (Y)'	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: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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.	(b) (4) 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'	Sarah Sandberg (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Acute incarcerated ventral Hernia'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '5/325'	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'mg (mg)'	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'four times daily (QID)'	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Oral (ORAL)'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '14 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'No (N)'	Sarah Sandberg (b) (4)	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User entered '804 (804)'	System	24 Sep 2020 16:25:56

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:40:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:39:08

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '10 Sep 2020'	Sarah Sandberg (b) (4)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Exploratory Laparotomy with repair of incarcerated recurrent ventral hernia with Phasix mesh Enterectomy with anastomosis'	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'Adverse Event (AE)'	Sarah Sandberg (b) (4)	24 Sep 2020 16:40:11

US3772051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	24 Sep 2020 16:40:11

US3772051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '28 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:29:25
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'SAE (specify) (SAE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	28 Sep 2020 23:29:25

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:21:08
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:37:22
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:07:52
Signature has been broken.	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:07:46
User entered 'SAE#1' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:07:46
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:20:15
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	19 Feb 2021 22:00:32
User closed 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)	25 Nov 2020 05:58:59
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 17:44:35
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 17:44:31
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) (b) (4)	18 Nov 2020 23:38:19

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
User entered 'USA-US107-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:38:14
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6) (b) (4)	18 Nov 2020 16:50:20
User entered 'Acute incarcerated ventral hernia'	Sarah Sandberg (b) (4) (b) (4)	28 Sep 2020 23:29:25

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '28 Sep 2020'	Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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) (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) (b) (4)	18 Nov 2020 23:38:45
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Emily Crews (b) (4) (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)'	Sarah Sandberg (b) (4) (b) (4)	28 Sep 2020 23:29:55

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:21:08
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:37:15
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:08:21
Signature has been broken.	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:08:14
User entered 'SAE #1' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:08:14
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:20:27
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	19 Feb 2021 22:00:32
User closed 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)	25 Nov 2020 05:59:14
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)	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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
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	Sarah Sandberg (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.	Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

US3772051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	28 Sep 2020 23:29:55

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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
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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '7'	(b) (4)	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
User entered '2'	(b) (4)	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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 'I'	(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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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
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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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 'I'	(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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '7'	(b) (4)	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
User entered '2'	(b) (4)	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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '18/Sep/2020 12:01'	(b) (4) System	18 Sep 2020 16:01:20

US3772051

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

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:55:03
User entered 'I'		18 Sep 2020 16:01:20

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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
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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '25/Sep/2020 10:55'	(b) (4) System	25 Sep 2020 14:55:26

US3772051

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

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 16:27:48
User entered 'I'	(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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '7'	(b) (4)	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
User entered '2'	(b) (4)	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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '30/Sep/2020 16:28'	(b) (4) System	30 Sep 2020 16:28:02

US3772051

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

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:48:55
User entered 'I'	(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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '7'	(b) (4)	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
User entered '2'	(b) (4)	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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '08/Oct/2020 12:49'	(b) (4) System	08 Oct 2020 16:49:05

US3772051

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

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:26:13
User entered 'I'	(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: 10 Jun 2021 09:40:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
Reviewed for Safety.	(b) (4) (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
User entered 'California'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 22:19:13

US3772051

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:40:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
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: 10 Jun 2021 09:40:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
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
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: 10 Jun 2021 09:40:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered '20/Oct/2020 14:26'	(b) (4) System	20 Oct 2020 14:26:27

US3772051

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

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:40:55

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	19 Feb 2021 22:00:32
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 14:26:27