

US3852200 (Prod: Ascension St. Vincent Birmingham)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:05:50

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US3852200

Form: Participant Creation

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

[Participant ID](#)

US3852200

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

US3852200

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:51 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:51
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	194 lb
BMI (<i>xxx.x</i>)	31.37789 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED/FOREHEAD
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 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) 09 Feb 2021 10:59:48

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Date of assessment (dd MMM yyyy) 13 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 13 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Feb 2021 10:59:48

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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

VOLUNTEER, CHURCH

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) 09 Feb 2021 10:59:48

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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) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

What was the date of randomization? (dd MMM yyyy) 22 OCT 2020

What was the participant's randomization number? 117863

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) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Height	66 in
Weight	194 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Height	66 in
Weight	194 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Height	66 in
Weight	194 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 14:22
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 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: Pregnancy Test

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 22 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

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) 22 OCT 2020

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 13:52

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) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	13:35 (24 HR)
Collection date and time (derived)	22 OCT 2020 13:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:20	22 OCT 2020 13:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

22 OCT 2020 14:25

PC Open Date & Time

22 OCT 2020 14:12

PC Close Date & Time

22 OCT 2020 16:42

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	22 OCT 2020 18:05
PC Open Date & Time	22 OCT 2020 17:37
PC Close Date & Time	23 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

23 OCT 2020 19:32

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 19:46

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

25 OCT 2020 20:01

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 18:48

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 19:27

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

28 OCT 2020 21:30

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 14:25

PC Open Date & Time

22 OCT 2020 14:12

PC Close Date & Time

22 OCT 2020 16:42

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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

22 OCT 2020 18:06

PC Open Date & Time

22 OCT 2020 17:37

PC Close Date & Time

23 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 ☐

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

10

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 19:33

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 ☐

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

7

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 19:47

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

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

25 OCT 2020 20:02

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

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

26 OCT 2020 18:48

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 19:27

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 21:31

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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 ☐

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 14:26
PC Open Date & Time	22 OCT 2020 14:12
PC Close Date & Time	22 OCT 2020 16:42

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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 ☐

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 18:07
PC Open Date & Time	22 OCT 2020 17:37
PC Close Date & Time	23 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 ☒

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	23 OCT 2020 19:34
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 ☒

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EAB) (1725)

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US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	24 OCT 2020 19:47
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	25 OCT 2020 20:02
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

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

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EAB) (1725)

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	26 OCT 2020 18:49
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	27 OCT 2020 19:27
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

Yes ☐	
PC Time stamp	28 OCT 2020 21:31
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3852200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

VOICEMAIL FOR DAY 8 SAFETY

CALL 9:28AM

If Contact Not Made, please provide Comments

US3852200

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852200

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852200

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

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

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

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

US3852200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

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.

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

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?

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?

US3852200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3852200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:05:50

Collection date (dd MMM yyyy)			
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3852200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852200

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3852200

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:59:48

Generated On: 10 Jun 2021 10:05:50

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3852200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:05:50

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

US3852200

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:05:50

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

US3852200

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:05:50

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3852200

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

AEID	USA-US076-2020-MRNA-1273-P30 1000006
Adverse event	KIDNEY STONES
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)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	29 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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EAB) (1725)

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US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

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

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

PATIENT REPORTED BEING
ADMITTED TO THE HOSPITAL
ON 23NOV WITH FEVER OF 104
AND PAIN ALL OVER TO THE
SAFETY NURSE. SHE ENDED UP
BEING DIAGNOSED WITH
KIDNEY STONES. SHE REPORTS
BEING ON IV ANTIBIOTICS AND
IS STILL IN THE HOSPITAL.
PATIENT REPORTS BEING
TESTED FOR COVID TWICE
AND BOTH ARE NEGATIVE

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

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

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

Yes ☒

No ☐

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

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3852200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3852200

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Feb 2021 10:59:47

Generated On: 10 Jun 2021 10:05:50

Date of dosing discontinuation (dd MMM yyyy) 8 DEC 2020

Primary reason for dosing discontinuation

AE (specify)	☐
SAE (specify)	☐
Death	☐
Lost To Follow-up	☒
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☐
Other	☐

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

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Apr 2021 01:23:37

Generated On: 10 Jun 2021 10:05:50

Date of study discontinuation/completion (dd MMM yyyy) 18 DEC 2020

Reason for discontinuation

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

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

PATIENT FAILS TO SHOW FOR APPOINTMENTS AND RETURN CALLS. ONLY ONE INJECTION GIVEN FOR VISIT 1.

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

SAEID	USA-US076-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

SAEID	USA-US076-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/NOV/2020 13:56
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

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

SAEID	USA-US076-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/DEC/2020 18:56
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

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

SAEID	USA-US076-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 14:04
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

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Mar 2021 04:39:28

Generated On: 10 Jun 2021 10:05:50

SAEID	USA-US076-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/FEB/2021 13:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3852200 (Prod: Ascension St. Vincent Birmingham)

US3852200

Form: Participant Creation

Generated On: 10 Jun 2021 10:05:50

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'US3852200'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:48:46

US3852200

Form: Participant Creation

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03

US3852200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:23

US3852200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:48:47

US3852200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:23

US3852200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'SCRN'	System	20 Oct 2020 20:51:23

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Per CDM: Please complete all forms for Screening. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 08:18:55
Query 'Per CDM: Please complete all forms for Screening. Thank you. ' answered with 'completing now' (Site from DM).	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 19:26:26
User opened query 'Per CDM: Please complete all forms for Screening. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:14:06
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:48:48

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '53'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'YEARS'	System	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '53'	System	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Female) and Year of Birth (1967) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 11:28:59
Query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Female) and Year of Birth (1967) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' answered with 'Sex and Year of Birth are correct as entered' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:57:43
User opened query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Female) and Year of Birth (1967) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:17:18
User entered 'Female (F)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '1'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	22 Oct 2020 19:24:24

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13 Oct 2020'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'Oct 2020'	System	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '2020'	System	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:22:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:22:46
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:22:35
User entered empty.	System	22 Oct 2020 19:22:35
	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35
	(b) (4)	

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:35

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:48:47

US3852200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '1'	System	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:05:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:00:55

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13 Oct 2020'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '12:51'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '13 Oct 2020 12:51'	System	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '66' in	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13
DataPoint set to visible.	System	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '194' lb	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13
DataPoint set to visible.	System	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '31.37789'	System	27 Oct 2020 18:02:13
DataPoint set to visible.	System	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'kg/m2'	System	27 Oct 2020 18:02:13
DataPoint set to visible.	System	22 Oct 2020 19:22:53

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '98.4' F	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'infrared/forehead'	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '74'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'bpm'	System	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '16'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'breaths/min'	System	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '118'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'mmHg'	System	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '68'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'mmHg'	System	27 Oct 2020 18:02:13

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11

US3852200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11

US3852200

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:32

US3852200

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '19 Oct 2020'	Jessica Bartlett (b) (4)	27 Oct 2020 18:02:32

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13 Oct 2020'	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:05:50

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:31:59

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13 Oct 2020'	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Urine (URINE)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Negative (NEGATIVE)'	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered empty.	System	27 Oct 2020 18:32:15

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'volunteer, church'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '1'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:35:33

US3852200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:43:25

US3852200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	Jessica Bartlett (b) (4)	22 Oct 2020 21:43:25

US3852200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Clinic (Clinic)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:43:25

US3852200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'VISIT1'	System	22 Oct 2020 21:43:25

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:23:51

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '117863'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:23:51

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:23:51

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:14

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:14

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:14

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:22:14

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 19:22:14

US3852200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 19:23:51
DataPoint set to visible.	(b) (4) System	22 Oct 2020 19:22:46

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '66' in	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '194' lb	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '66' in	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '194' lb	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User accepted default value 'Pre-Dose (PREDOSE)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13:10'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered '22 Oct 2020 13:10'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '97.8' F	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'infrared/forehead'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '71'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'bpm'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '18'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'breaths/min'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '138'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'mmHg'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '73'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'mmHg'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '66' in	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '194' lb	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User accepted default value 'Post-Dose (POSTDOSE)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 21:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 21:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:02
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 21:44:57
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Oct 2020 21:45:17
User entered '22 Oct 2020' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:17
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 21:45:02
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Oct 2020 21:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Oct 2020 21:45:17
User entered '14:22' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Oct 2020 21:45:02
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57
	(b) (4)	

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered '22 Oct 2020 14:22'	System	22 Oct 2020 21:45:17
User entered empty.	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '98.2' F	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Other (Other)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'infrared/forehead'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '75'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'bpm'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '16'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'breaths/min'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '116'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'mmHg'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '68'	Jessica Bartlett (b) (4)	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered 'mmHg'	System	22 Oct 2020 21:44:57

US3852200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:24

US3852200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:24

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Urine (URINE)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Negative (NEGATIVE)'	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Jessica Bartlett (b) (4)	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:32
User entered empty.	System	27 Oct 2020 18:36:15

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13:52'	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '22 Oct 2020 13:52'	System	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Left Arm (LEFT ARM)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'ONCE'	System	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 19:23:30

US3852200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:50

US3852200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:50

US3852200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13:35' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 21:46:24
User entered '15:35'	Jessica Bartlett (b) (4)	22 Oct 2020 21:45:50
	(b) (4)	

US3852200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '22 Oct 2020 13:35'	System	22 Oct 2020 21:46:24
User entered '22 Oct 2020 15:35'	System	22 Oct 2020 21:45:50

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:05:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '22 Oct 2020'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '13:20'	Jessica Bartlett (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '22 Oct 2020 13:20'	System	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered empty.	System	22 Oct 2020 21:46:17

US3852200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	22 Oct 2020 19:23:40

US3852200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '1'	System	22 Oct 2020 19:23:40

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:24:40', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '4ae59bd1-58bc-481f-9ae9-72540e062bc5' User entered 'Yes (Y)'	System	22 Oct 2020 19:25:07
	System	22 Oct 2020 19:25:07

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:24:48', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '4ae59bd1-58bc-481f-9ae9-72540e062bc5' User entered '98.2'	System	22 Oct 2020 19:25:07
	System	22 Oct 2020 19:25:07

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:24:54', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '4ae59bd1-58bc-481f-9ae9-72540e062bc5'	System	22 Oct 2020 19:25:07
User entered 'No (N)'	System	22 Oct 2020 19:25:07

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:03', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '4ae59bd1-58bc-481f-9ae9-72540e062bc5' User entered '22 Oct 2020 14:25'	System	22 Oct 2020 19:25:07
	System	22 Oct 2020 19:25:07

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 14:12'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 16:42'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:05:03', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd7498467-efb3-42b4-bf18-c2bdeb857527' User entered 'Yes (Y)'	System	22 Oct 2020 23:05:21
	System	22 Oct 2020 23:05:21

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:05:08', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd7498467-efb3-42b4-bf18-c2bdeb857527' User entered '98.7'	System	22 Oct 2020 23:05:21
	System	22 Oct 2020 23:05:21

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:05:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd7498467-efb3-42b4-bf18-c2bdeb857527'	System	22 Oct 2020 23:05:21
User entered 'No (N)'	System	22 Oct 2020 23:05:21

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:05:19', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd7498467-efb3-42b4-bf18-c2bdeb857527' User entered '22 Oct 2020 18:05'	System	22 Oct 2020 23:05:21
	System	22 Oct 2020 23:05:21

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 17:37'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 2'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:31:52', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '5c76e31b-f21d-4008-84de-22328fa7226f' User entered 'Yes (Y)'	System	24 Oct 2020 00:32:09
	System	24 Oct 2020 00:32:09

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:31:58', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '5c76e31b-f21d-4008-84de-22328fa7226f' User entered '98.0'	System	24 Oct 2020 00:32:09
	System	24 Oct 2020 00:32:09

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:32:01', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '5c76e31b-f21d-4008-84de-22328fa7226f' User entered 'No (N)'	System	24 Oct 2020 00:32:09
	System	24 Oct 2020 00:32:09

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:32:06', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '5c76e31b-f21d-4008-84de-22328fa7226f' User entered '23 Oct 2020 19:32'	System	24 Oct 2020 00:32:09
	System	24 Oct 2020 00:32:09

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 3'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:46:31', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9e172a25-109d-401e-ab24-cb4465bbc9fb' User entered 'Yes (Y)'	System	25 Oct 2020 00:46:49
	System	25 Oct 2020 00:46:49

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:46:35', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9e172a25-109d-401e-ab24-cb4465bbc9fb' User entered '97.8'	System	25 Oct 2020 00:46:49
	System	25 Oct 2020 00:46:49

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:46:38', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9e172a25-109d-401e-ab24-cb4465bbc9fb' User entered 'No (N)'	System	25 Oct 2020 00:46:49
	System	25 Oct 2020 00:46:49

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:46:47', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9e172a25-109d-401e-ab24-cb4465bbc9fb' User entered '24 Oct 2020 19:46'	System	25 Oct 2020 00:46:49
	System	25 Oct 2020 00:46:49

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 4'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:25', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7cfa53f5-79d9-4e79-95a9-008cae190f42' User entered 'Yes (Y)'	System	26 Oct 2020 01:01:45
	System	26 Oct 2020 01:01:45

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:31', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7cfa53f5-79d9-4e79-95a9-008cae190f42' User entered '97.3'	System	26 Oct 2020 01:01:45
	System	26 Oct 2020 01:01:45

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:36', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7cfa53f5-79d9-4e79-95a9-008cae190f42'	System	26 Oct 2020 01:01:45
User entered 'No (N)'	System	26 Oct 2020 01:01:45

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:43', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7cfa53f5-79d9-4e79-95a9-008cae190f42'	System	26 Oct 2020 01:01:45
User entered '25 Oct 2020 20:01'	System	26 Oct 2020 01:01:45

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 5'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:23', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '16412c73-5656-4a68-bfad-fe336e51e8b7' User entered 'Yes (Y)'	System	26 Oct 2020 23:48:42
	System	26 Oct 2020 23:48:42

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:31', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '16412c73-5656-4a68-bfad-fe336e51e8b7' User entered '98.5'	System	26 Oct 2020 23:48:42
	System	26 Oct 2020 23:48:42

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:33', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '16412c73-5656-4a68-bfad-fe336e51e8b7'	System	26 Oct 2020 23:48:42
User entered 'No (N)'	System	26 Oct 2020 23:48:42

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:39', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '16412c73-5656-4a68-bfad-fe336e51e8b7' User entered '26 Oct 2020 18:48'	System	26 Oct 2020 23:48:42
	System	26 Oct 2020 23:48:42

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 6'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:08', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'f34c1053-69b3-4597-a363-b20f41bb3f0b' User entered 'Yes (Y)'	System	28 Oct 2020 00:27:24
	System	28 Oct 2020 00:27:24

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'f34c1053-69b3-4597-a363-b20f41bb3f0b' User entered '97.6'	System	28 Oct 2020 00:27:24
	System	28 Oct 2020 00:27:24

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:16', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'f34c1053-69b3-4597-a363-b20f41bb3f0b' User entered 'No (N)'	System	28 Oct 2020 00:27:24
	System	28 Oct 2020 00:27:24

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:20', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'f34c1053-69b3-4597-a363-b20f41bb3f0b' User entered '27 Oct 2020 19:27'	System	28 Oct 2020 00:27:24
	System	28 Oct 2020 00:27:24

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 7'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:30:33', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'c0925209-f78f-4409-98e8-51d0eac03a2a' User entered 'Yes (Y)'	System	29 Oct 2020 02:30:55
	System	29 Oct 2020 02:30:55

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:30:37', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'c0925209-f78f-4409-98e8-51d0eac03a2a' User entered '97.3'	System	29 Oct 2020 02:30:55
	System	29 Oct 2020 02:30:55

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:30:41', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'c0925209-f78f-4409-98e8-51d0eac03a2a' User entered 'No (N)'	System	29 Oct 2020 02:30:55
	System	29 Oct 2020 02:30:55

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:30:52', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'c0925209-f78f-4409-98e8-51d0eac03a2a' User entered '28 Oct 2020 21:30'	System	29 Oct 2020 02:30:55
	System	29 Oct 2020 02:30:55

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:32', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9127dac4-7723-46a4-99f1-047eec10beae' User entered 'None (1)'	System	22 Oct 2020 19:25:56
	System	22 Oct 2020 19:25:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:39', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9127dac4-7723-46a4-99f1-047eec10beae' User entered 'No (N)'	System	22 Oct 2020 19:25:56
	System	22 Oct 2020 19:25:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:43', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9127dac4-7723-46a4-99f1-047eec10beae' User entered 'No (N)'	System	22 Oct 2020 19:25:56
	System	22 Oct 2020 19:25:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:48', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9127dac4-7723-46a4-99f1-047eec10beae' User entered 'None (1)'	System	22 Oct 2020 19:25:56
	System	22 Oct 2020 19:25:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:25:54', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9127dac4-7723-46a4-99f1-047eec10beae' User entered '22 Oct 2020 14:25'	System	22 Oct 2020 19:25:56
	System	22 Oct 2020 19:25:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 14:12'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 16:42'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:05:32', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '07f95b2b-09ae-4bfb-a1e9-6fa0dfe16378'	System	22 Oct 2020 23:06:46
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 23:06:46

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:06:24', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '07f95b2b-09ae-4bfb-a1e9-6fa0dfe16378' User entered 'No (N)'	System	22 Oct 2020 23:06:46
	System	22 Oct 2020 23:06:46

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:06:27', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '07f95b2b-09ae-4bfb-a1e9-6fa0dfe16378' User entered 'No (N)'	System	22 Oct 2020 23:06:46
	System	22 Oct 2020 23:06:46

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:06:34', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '07f95b2b-09ae-4bfb-a1e9-6fa0dfe16378'	System	22 Oct 2020 23:06:46
User entered 'None (1)'	System	22 Oct 2020 23:06:46

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:06:40', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '07f95b2b-09ae-4bfb-a1e9-6fa0dfe16378' User entered '22 Oct 2020 18:06'	System	22 Oct 2020 23:06:46
	System	22 Oct 2020 23:06:46

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '22 Oct 2020 17:37'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 2'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:32:38', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed'	System	24 Oct 2020 00:33:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:32:52', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed' User entered 'Yes (Y)'	System	24 Oct 2020 00:33:54
	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:25', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed' User entered '10'	System	24 Oct 2020 00:33:54
	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:33', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed' User entered 'No (N)'	System	24 Oct 2020 00:33:54
	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:36', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed' User entered 'None (1)'	System	24 Oct 2020 00:33:54
	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:51', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '9680e3d2-16e4-496a-ae2b-93096b4a4aed' User entered '23 Oct 2020 19:33'	System	24 Oct 2020 00:33:54
	System	24 Oct 2020 00:33:54

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 3'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:46:53', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2'	System	25 Oct 2020 00:47:24
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:01', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2'	System	25 Oct 2020 00:47:24
User entered 'Yes (Y)'	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:07', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2' User entered '7'	System	25 Oct 2020 00:47:24
	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2' User entered 'No (N)'	System	25 Oct 2020 00:47:24
	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:16', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2'	System	25 Oct 2020 00:47:24
User entered 'None (1)'	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:23', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '45584a49-8045-4ee8-8e05-d4b2f5ab75d2' User entered '24 Oct 2020 19:47'	System	25 Oct 2020 00:47:24
	System	25 Oct 2020 00:47:24

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 4'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:46', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'e41d7681-1e00-4bee-a05e-2469e35642c7'	System	26 Oct 2020 01:02:03
User entered 'None (1)'	System	26 Oct 2020 01:02:03

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:49', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'e41d7681-1e00-4bee-a05e-2469e35642c7' User entered 'No (N)'	System	26 Oct 2020 01:02:03
	System	26 Oct 2020 01:02:03

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:56', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'e41d7681-1e00-4bee-a05e-2469e35642c7' User entered 'No (N)'	System	26 Oct 2020 01:02:03
	System	26 Oct 2020 01:02:03

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:01:58', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'e41d7681-1e00-4bee-a05e-2469e35642c7' User entered 'None (1)'	System	26 Oct 2020 01:02:03
	System	26 Oct 2020 01:02:03

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:01', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'e41d7681-1e00-4bee-a05e-2469e35642c7' User entered '25 Oct 2020 20:02'	System	26 Oct 2020 01:02:03
	System	26 Oct 2020 01:02:03

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 5'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:43', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '3b195bcb-d4a2-474c-bed1-d0fdf8b9a228'	System	26 Oct 2020 23:48:56
User entered 'None (1)'	System	26 Oct 2020 23:48:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:45', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '3b195bcb-d4a2-474c-bed1-d0fdf8b9a228' User entered 'No (N)'	System	26 Oct 2020 23:48:56
	System	26 Oct 2020 23:48:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:47', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '3b195bcb-d4a2-474c-bed1-d0fdf8b9a228' User entered 'No (N)'	System	26 Oct 2020 23:48:56
	System	26 Oct 2020 23:48:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:49', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '3b195bcb-d4a2-474c-bed1-d0fdf8b9a228' User entered 'None (1)'	System	26 Oct 2020 23:48:56
	System	26 Oct 2020 23:48:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:52', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '3b195bcb-d4a2-474c-bed1-d0fdf8b9a228' User entered '26 Oct 2020 18:48'	System	26 Oct 2020 23:48:56
	System	26 Oct 2020 23:48:56

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 6'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:24', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7eec75fe-8f36-44d4-9f6a-6f0f29f54f9e'	System	28 Oct 2020 00:27:36
User entered 'None (1)'	System	28 Oct 2020 00:27:36

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:26', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7eec75fe-8f36-44d4-9f6a-6f0f29f54f9e'	System	28 Oct 2020 00:27:36
User entered 'No (N)'	System	28 Oct 2020 00:27:36

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:28', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7eec75fe-8f36-44d4-9f6a-6f0f29f54f9e'	System	28 Oct 2020 00:27:36
User entered 'No (N)'	System	28 Oct 2020 00:27:36

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:29', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7eec75fe-8f36-44d4-9f6a-6f0f29f54f9e'	System	28 Oct 2020 00:27:36
User entered 'None (1)'	System	28 Oct 2020 00:27:36

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:32', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '7eec75fe-8f36-44d4-9f6a-6f0f29f54f9e' User entered '27 Oct 2020 19:27'	System	28 Oct 2020 00:27:36
	System	28 Oct 2020 00:27:36

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 7'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:30:57', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'fd7c5421-90eb-4d4c-b853-23dbfe185735'	System	29 Oct 2020 02:31:27
User entered 'None (1)'	System	29 Oct 2020 02:31:27

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:09', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'fd7c5421-90eb-4d4c-b853-23dbfe185735'	System	29 Oct 2020 02:31:27
User entered 'No (N)'	System	29 Oct 2020 02:31:27

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:15', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'fd7c5421-90eb-4d4c-b853-23dbfe185735' User entered 'No (N)'	System	29 Oct 2020 02:31:27
	System	29 Oct 2020 02:31:27

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

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 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:21', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'fd7c5421-90eb-4d4c-b853-23dbfe185735'	System	29 Oct 2020 02:31:27
User entered 'None (1)'	System	29 Oct 2020 02:31:27

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:24', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'fd7c5421-90eb-4d4c-b853-23dbfe185735' User entered '28 Oct 2020 21:31'	System	29 Oct 2020 02:31:27
	System	29 Oct 2020 02:31:27

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:06
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:01', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:04', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:06', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:09', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:12', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:15', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'None (0)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:18', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337' User entered 'No (N)'	System	22 Oct 2020 19:26:23
	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T14:26:20', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ccd39796-5b34-4ead-97d4-54a40ba75337'	System	22 Oct 2020 19:26:23
User entered '22 Oct 2020 14:26'	System	22 Oct 2020 19:26:23

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '22 Oct 2020 14:12'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '22 Oct 2020 16:42'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:06:46', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:16', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:19', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:21', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:24', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'None (0)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:29', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered 'No (N)'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-22T18:07:33', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '804ded4f-2b15-4d75-aa9b-ea1263559812' User entered '22 Oct 2020 18:07'	System	22 Oct 2020 23:07:39
	System	22 Oct 2020 23:07:39

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '22 Oct 2020 17:37'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 2'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:56', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:33:59', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:02', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:04', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:06', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:08', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'None (0)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:11', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered 'No (N)'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-23T19:34:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'bea206e5-eb0d-4f43-83a1-412fe4bb6b4a' User entered '23 Oct 2020 19:34'	System	24 Oct 2020 00:34:15
	System	24 Oct 2020 00:34:15

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 3'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:27', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:29', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:31', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:33', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:34', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:36', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'None (0)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:38', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered 'No (N)'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-24T19:47:41', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'd2b87502-62ee-481b-9882-5fd55a8211b1' User entered '24 Oct 2020 19:47'	System	25 Oct 2020 00:47:45
	System	25 Oct 2020 00:47:45

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 4'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:04', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:05', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:07', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:08', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:09', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:11', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'None (0)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:13', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered 'No (N)'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-25T20:02:15', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '0ee9b76f-4c39-4be8-bb22-460b55dee88c' User entered '25 Oct 2020 20:02'	System	26 Oct 2020 01:02:17
	System	26 Oct 2020 01:02:17

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 5'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:56', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:48:58', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:00', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:02', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:03', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:05', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered 'None (0)'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:08', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933'	System	26 Oct 2020 23:49:12
User entered 'No (N)'	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-26T18:49:11', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ef6ddd1a-67eb-446a-b219-1755dac65933' User entered '26 Oct 2020 18:49'	System	26 Oct 2020 23:49:12
	System	26 Oct 2020 23:49:12

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 6'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:37', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:38', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:40', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:43', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:45', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:47', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'None (0)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:49', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered 'No (N)'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-27T19:27:52', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: '294c2734-4f78-4987-8b00-b50643f5029f' User entered '27 Oct 2020 19:27'	System	28 Oct 2020 00:27:57
	System	28 Oct 2020 00:27:57

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
Data entry locked.	System	22 Oct 2020 19:23:30
User entered 'Day 7'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:30', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:34', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:36', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:38', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:42', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:44', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'None (0)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

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 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:47', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered 'No (N)'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1346F1A0-E219-4812-AC6D-68E0DB9D0917)', Time: '2020-10-28T21:31:50', User OID: 'PatientReportedOutcome (US3852200)', ODM File OID: 'ba5ae854-caf4-46f6-94a6-d1b6fb3f25d5' User entered '28 Oct 2020 21:31'	System	29 Oct 2020 02:31:55
	System	29 Oct 2020 02:31:55

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:23:30

US3852200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:04
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:23:30

US3852200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	29 Oct 2020 14:28:27

US3852200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '29 Oct 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	29 Oct 2020 14:28:27

US3852200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	29 Oct 2020 16:32:59
reason for change: New Information	Jasmine Ali (b) (4)	29 Oct 2020 14:28:27
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	

US3852200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'voicemail for day 8 safety call 9:28am'	(b) (4) Jasmine Ali (b) (4) (b) (4)	29 Oct 2020 14:28:27

US3852200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	29 Oct 2020 16:33:05

US3852200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '1'	System	29 Oct 2020 16:33:05

US3852200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:07

US3852200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '6 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:07

US3852200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:07

US3852200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:07

US3852200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:13

US3852200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '1'	System	06 Nov 2020 14:41:13

US3852200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	12 Nov 2020 14:48:40

US3852200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '12 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	12 Nov 2020 14:48:40

US3852200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	12 Nov 2020 14:48:40

US3852200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	12 Nov 2020 14:48:40

US3852200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	12 Nov 2020 14:48:47

US3852200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:23:11
User entered '1'	System	12 Nov 2020 14:48:47

US3852200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Lisa Huse (b) (4)	08 Dec 2020 19:23:56

US3852200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:23:56

US3852200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:23:56

US3852200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered 'VISIT2'	System	08 Dec 2020 19:23:56

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Huse (b) (4) (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Huse (b) (4) (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:04

US3852200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Lisa Huse (b) (4)	08 Dec 2020 19:24:10

US3852200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:10

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User closed query 'Per CDM RQ: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:48:26
Query 'Per CDM RQ: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' ' answered with 'Per previous query response-subject did not get treatment dosing, so pregnancy test not done. Visit was rescheduled and then cancelled.' (Site from DM).	Leslie Edwards (b) (4)	05 Apr 2021 15:03:17
User opened query 'Per CDM RQ: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 14:38:11
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 14:38:01
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" answered with 'Not done because she did not receive injection that day and did not return to complete visit.' (Site from DM).	Leslie Edwards (b) (4)	22 Mar 2021 15:19:10
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:22:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:16

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Lisa Huse (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Per CDM: Please verify data and complete the End of study page, since subject did NOT receive IP and was "Lost to follow-up" on the study. Else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 05:21:45
Query 'Per CDM: Please verify data and complete the End of study page, since subject did NOT receive IP and was "Lost to follow-up" on the study. Else clarify. Thank you. ' answered with 'Pages completed' (Site from DM).	Jessica Bartlett (b) (4) (b) (4)	08 Jan 2021 16:26:34
User opened query 'Per CDM: Please verify data and complete the End of study page, since subject did NOT receive IP and was "Lost to follow-up" on the study. Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 14:53:09
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		09 Dec 2020 17:45:49
User entered 'Lost To Follow-Up (LOST TO FOLLOW-UP)' reason for change: New Information	Leslie Edwards (b) (4) (b) (4)	09 Dec 2020 17:45:49
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	08 Dec 2020 19:24:23
User entered empty.	Lisa Huse (b) (4) (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	08 Dec 2020 19:24:23

US3852200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Leslie Edwards (b) (4)	09 Dec 2020 17:46:01

US3852200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Leslie Edwards (b) (4)	09 Dec 2020 17:46:01

US3852200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Leslie Edwards (b) (4)	09 Dec 2020 17:46:01

US3852200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	09 Dec 2020 17:46:01

US3852200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:09:47

US3852200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered '1'	System	08 Dec 2020 15:09:47

US3852200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Leslie Edwards (b) (4)	05 Feb 2021 16:44:16

US3852200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Leslie Edwards (b) (4)	05 Feb 2021 16:44:16

US3852200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Leslie Edwards (b) (4)	05 Feb 2021 16:44:16

US3852200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Leslie Edwards (b) (4)	05 Feb 2021 16:44:16

US3852200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:31:53

US3852200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered '1'	System	08 Dec 2020 15:31:53

US3852200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 15:25:11
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 16:44:42

US3852200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:25:11
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 16:44:42

US3852200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:25:11
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Leslie Edwards (b) (4) (b) (4)	05 Feb 2021 16:44:42

US3852200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:25:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
	(b) (4)	
User entered empty.	Leslie Edwards (b) (4)	05 Feb 2021 16:44:42
	(b) (4)	

US3852200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:25:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
	(b) (4)	
User entered 'No (N)'	Leslie Edwards (b) (4)	05 Feb 2021 16:44:46
	(b) (4)	

US3852200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:25:11
User entered empty.	System	05 Feb 2021 16:44:46

US3852200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jessica Bartlett (b) (4)	27 Nov 2020 21:37:35
User entered 'No (N)'	(b) (4)	
	Jessica Bartlett (b) (4)	22 Oct 2020 21:46:41
	(b) (4)	

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:20
User entered 'USA-US076-2020-mRNA-1273-P301000006'	System	30 Nov 2020 13:56:15
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 13:56:15

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User coded data point as SOC: Renal and urinary disorders, HLG: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	27 Nov 2020 21:42:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 21:42:18
Data point term sent to Coder	System	27 Nov 2020 21:41:00
User entered 'Kidney stones'	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '23 Nov 2020'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	15 Jan 2021 17:00:11
User entered 'Yes (Y)'	(b) (4)	
	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49
	(b) (4)	

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
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) (4), (b) (6)	19 Jan 2021 14:04:01
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 'Updated' (Site from Safety).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 17:00:45
User entered '29 Nov 2020' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 17:00:11
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)	09 Dec 2020 21:23:40
User entered empty.	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'PV Query: Please confirm the severity of the event, because the event lead to hospitalization.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:03:59
Query 'PV Query: Please confirm the severity of the event, because the event lead to hospitalization.' answered with 'Updated' (Site from Safety).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 17:00:51
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 17:00:11
User opened query 'PV Query: Please confirm the severity of the event, because the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:26:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Per CDM Re-query: Please update the 'Hospital Discharge Date' when available and route back to DM review . Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 09:51:45
Query 'Per CDM Re-query: Please update the 'Hospital Discharge Date' when available and route back to DM review . Thank you.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	02 Dec 2020 20:15:35
User opened query 'Per CDM Re-query: Please update the 'Hospital Discharge Date' when available and route back to DM review . Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:23:10
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)	01 Dec 2020 13:22:09
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 'hospital admission date is listed. Will get more information once I speak with the patient' (Site from System).	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:42:01
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	27 Nov 2020 21:40:49
User entered '1'	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '23 Nov 2020'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
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)	
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 'Records unable to obtain. Subject withdrew from study immediately following hospitalization and did not receive second visit.' (Site from Safety).	Leslie Edwards (b) (4)	26 Jan 2021 16:01:30
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)	25 Jan 2021 18:37:12
User entered '29 Nov 2020' reason for change: Data Entry Error	Leslie Edwards (b) (4)	02 Dec 2020 20:15:18
User entered empty.	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	30 Nov 2020 03:41:54
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		30 Nov 2020 03:41:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 03:41:54
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	27 Nov 2020 21:40:49
User entered 'Unknown (UNK)'	Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

US3852200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Not Related (NOT RELATED)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Not Related (NOT RELATED)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Dose Delayed (DOSE DELAYED)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Signature has been broken.	(b) (4)	
	Lisa Huse (b) (4)	16 Feb 2021 21:03:40
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Huse (b) (4)	16 Feb 2021 21:03:40
	(b) (4)	
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
	(b) (4)	
User entered '0'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4)	17 Feb 2021 10:29:00
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Lisa Huse (b) (4)	16 Feb 2021 21:04:36
' answered with 'Subject no longer in the study due to not responding to calls or texts. No access to explore if there were Con Meds associated to this diagnosis. '	(b) (4)	
(Site from DM).		
Signature has been broken.	Lisa Huse (b) (4)	16 Feb 2021 21:03:40
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Lisa Huse (b) (4)	16 Feb 2021 21:03:40
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 07:46:45
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '1'	(b) (4)	
	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
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) (4), (b) (6)	19 Jan 2021 14:03:55
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 'Updated' (Site from Safety).	Leslie Edwards (b) (4)	15 Jan 2021 17:02:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Leslie Edwards (b) (4)	15 Jan 2021 17:00:11
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)	09 Dec 2020 21:24:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:03:54
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:03:52
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:03:49
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'None' (Site from Safety).	Leslie Edwards (b) (4)	15 Jan 2021 17:02:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Unable to obtain-unenrolled from study' (Site from Safety).	Leslie Edwards (b) (4)	15 Jan 2021 17:01:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Unable to obtain-unenrolled from study' (Site from Safety).	Leslie Edwards (b) (4)	15 Jan 2021 17:01:44
Query 'PV Query: Please confirm the severity of the event, because the event lead to hospitalization.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:26:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the severity of the event, because the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:26:15
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:24:57
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)	09 Dec 2020 21:24:29
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)	09 Dec 2020 21:24:03
User entered 'PATIENT REPORTED BEING ADMITTED TO THE HOSPITAL ON 23NOV WITH FEVER OF 104 AND PAIN ALL OVER TO THE SAFETY NURSE. SHE ENDED UP BEING DIAGNOSED WITH KIDNEY STONES. SHE REPORTS BEING ON IV ANTIBIOTICS AND IS STILL IN THE HOSPITAL. Patient reports being tested for COVID twice and both are negative' reason for change: Data Entry Error	Jessica Bartlett (b) (4)	27 Nov 2020 21:42:54
User entered 'Patient reported being admitted to the hospital on 23NOV with fever of 104 and pain all over to the safety nurse. She ended up being diagnosed with kidney stones. She reports being on IV antibiotics and is still in the hospital'	Jessica Bartlett (b) (4)	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered '1'	System	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered '1'	System	27 Nov 2020 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered '0'	System	27 Nov 2020 21:40:49

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:05:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 (23OCT2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:57:12
Query 'Per DM CLR: Per Diary Dose 1 Day 2 (23OCT2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject did not report medication to use to safety nurse. She has withdrawn from study and we are unable to get this information.' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	03 Feb 2021 20:56:04
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 (23OCT2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:21:14
User entered 'Yes (Y)' reason for change: New Information	Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:41:26
User entered 'No (N)'	Jessica Bartlett (b) (4) (b) (4)	22 Oct 2020 21:46:46

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 19:36:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 19:36:02
Data point term sent to Coder	System	04 Feb 2021 19:35:27
Coding entries removed.	Leslie Edwards (b) (4)	04 Feb 2021 19:34:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:44:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:44:17
Data point term sent to Coder	System	06 Nov 2020 14:42:51
User entered 'Influenza Vaccine'	Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Prophylaxis for influenza' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 19:34:43
User entered 'Flu Shot'	Leslie Edwards (b) (4)	04 Feb 2021 19:34:43
	(b) (4)	
	Martha Bunnell-Pollak	06 Nov 2020 14:42:11
	(b) (4)	

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0.5' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 19:34:43
User entered '1'	Leslie Edwards (b) (4)	04 Feb 2021 19:34:43
	(b) (4)	
	Martha Bunnell-Pollak	06 Nov 2020 14:42:11
	(b) (4)	

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 19:34:43
User entered 'Other (OTHER)'	Leslie Edwards (b) (4)	04 Feb 2021 19:34:43
	(b) (4)	
	Martha Bunnell-Pollak	06 Nov 2020 14:42:11
	(b) (4)	

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty; reason for change Data Entry Error	(b) (4)	04 Feb 2021 19:34:43
User entered 'Injection'	Leslie Edwards (b) (4)	06 Nov 2020 14:42:11
	(b) (4)	

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'once (ONCE)'	(b) (4) Martha Bunnell-Pollak	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '6 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '6 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User entered empty.	System	06 Nov 2020 14:42:11

US3852200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:05:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'No (N)'	Jessica Bartlett (b) (4)	22 Oct 2020 21:46:36

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:05:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '8 Dec 2020'	Lisa Huse (b) (4)	10 Dec 2020 18:55:15

US3852200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:05:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Lisa Huse (b) (4)	10 Dec 2020 18:55:15

US3852200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:05:50

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)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	10 Dec 2020 18:55:15

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '18 Dec 2020'	Lisa Huse (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:11:24
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 13:11:24
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

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)	29 Apr 2021 05:27:25
User closed query 'Per CDM: According to the Other, Specify comment, non compliance is the reason for discontinuation and this should be captured under the reason Protocol Deviation. Please confirm and amend Reason for Discontinuation.' (Site from DM). Query 'Per CDM: According to the Other, Specify comment, non compliance is the reason for discontinuation and this should be captured under the reason Protocol Deviation. Please confirm and amend Reason for Discontinuation.' answered with 'corrected to protocol deviation' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:51:40
User opened query 'Per CDM: According to the Other, Specify comment, non compliance is the reason for discontinuation and this should be captured under the reason Protocol Deviation. Please confirm and amend Reason for Discontinuation.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:11:47
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered 'Patient fails to show for appointments and return calls. Only one injection given for Visit 1.'	Lisa Huse (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	(b) (4) Lisa Huse (b) (4) (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:50

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered empty.	Lisa Huse (b) (4)	18 Dec 2020 18:55:19

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'USA-US076-2020-MRNA-1273-P301000006'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Leland'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Leland'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Allen'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Allen'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered 'US'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered '4'	System	17 Feb 2021 18:20:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '3'	System	19 Jan 2021 14:04:17
User entered '2'	System	03 Dec 2020 18:56:10
User entered '1'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'USA-US076-2020-MRNA-1273-P301000006'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Leland'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Leland'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Allen'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Allen'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered 'US'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered '4'	System	17 Feb 2021 18:20:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '3'	(b) (4)	19 Jan 2021 14:04:17
User entered '2'	System	03 Dec 2020 18:56:10
User entered '1'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:05:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '30/Nov/2020 13:56'	(b) (4) System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:05:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'USA-US076-2020-MRNA-1273-P301000006'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Leland'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Leland'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Allen'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Allen'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered 'US'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered '4'	System	17 Feb 2021 18:20:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '3'	(b) (4)	19 Jan 2021 14:04:17
User entered '2'	System	03 Dec 2020 18:56:10
User entered '1'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:05:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '03/Dec/2020 18:56'	(b) (4) System	03 Dec 2020 18:56:10

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:05:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:04:07
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 18:56:10

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'USA-US076-2020-MRNA-1273-P301000006'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Leland'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Leland'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Allen'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Allen'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered 'US'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered '4'	System	17 Feb 2021 18:20:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '3'	(b) (4)	19 Jan 2021 14:04:17
User entered '2'	System	03 Dec 2020 18:56:10
User entered '1'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:05:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '19/Jan/2021 14:04'	(b) (4) System	19 Jan 2021 14:04:17

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:05:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '1'	(b) (4), (b) (6)	19 Jan 2021 14:04:17

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'USA-US076-2020-MRNA-1273-P301000006'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Yes (Y)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'No (N)'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Leland'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Leland'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered 'Allen'	System	17 Feb 2021 18:20:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 18:20:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	19 Jan 2021 14:04:17
Reviewed for Safety.	System	19 Jan 2021 14:04:17
	(b) (4), (b) (6)	30 Nov 2020 13:56:39
User entered 'Allen'	System	30 Nov 2020 13:56:15

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 20:49:03

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 18:56:03
User entered 'US'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
Signature has been broken.	System	17 Feb 2021 18:20:49
User entered '4'	System	17 Feb 2021 18:20:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:59:49
User entered '3'	System	19 Jan 2021 14:04:17
User entered '2'	System	03 Dec 2020 18:56:10
User entered '1'	System	30 Nov 2020 13:56:43

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:05:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
User entered '17/Feb/2021 13:20'	(b) (4) System	17 Feb 2021 18:20:49

US3852200

Folder: SAE USA-US076-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:05:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:05
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:39:28
User entered '1'	(b) (4), (b) (6)	17 Feb 2021 18:20:49