

US3302395 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

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US3302395

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

[Participant ID](#)

US3302395

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

US3302395

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 AUG 2020

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

Folder OID SCRN

US3302395

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3302395

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Date of Informed Consent (*dd MMM yyyy*) 27 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3302395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Did the participant meet all eligibility criteria?

Yes

No

US3302395

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Were any significant conditions reported?

Yes

No

US3302395

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Condition	SENSORIMOTOR NEUROPATHY IN BILATERAL FEET
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3302395

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3302395

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 27 AUG 2020

Time of assessment (00:00-23:59) 08:22 (24 HR)

Vital Signs Date and Time (derived) 27 AUG 2020 08:22

Height (xxx.x) 74 in

Weight (xxx.x) 180 lb

BMI (xxx.x) 23.15895 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3302395

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3302395

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes No

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes No

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes No

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes No

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes No

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes No

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes No

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes No

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes No

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes No

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes No

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3302395

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:42:04

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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	

US3302395

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 AUG 2020

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

Folder OID VISIT1

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188326

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

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Height	ND - Not Done
Weight	ND - Not Done

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:22 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 08:22
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:34 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:34
Temperature (<i>xxx.x</i>)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3302395

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

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.

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 09:04 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 09:04

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

US3302395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 AUG 2020
Collection time (<i>00:00-23:59</i>)	08:35 (24 HR)
Collection date and time (derived)	27 AUG 2020 08:35

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Collection date (<i>dd MMM yyyy</i>)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:33	27 AUG 2020 08:33
Nasopharyngeal Swab 2	No		

US3302395

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp 27 AUG 2020 09:25

PC Open Date & Time 27 AUG 2020 09:24

PC Close Date & Time 27 AUG 2020 11:54

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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 98.0 °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 27 AUG 2020 13:09
PC Open Date & Time 27 AUG 2020 12:49
PC Close Date & Time 28 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 12:47
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 12:35
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 12:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 SEP 2020 12:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 14:35
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	27 AUG 2020 09:26
PC Open Date & Time	27 AUG 2020 09:24
PC Close Date & Time	27 AUG 2020 11:54

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

27 AUG 2020 13:10

PC Open Date & Time

27 AUG 2020 12:49

PC Close Date & Time

28 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 2

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

28 AUG 2020 12:48

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 3

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

29 AUG 2020 12:35

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 4

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

30 AUG 2020 12:04

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 5

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	31 AUG 2020 12:03
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 6

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

01 SEP 2020 12:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 7

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

02 SEP 2020 14:35

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

No

Yes

PC Time stamp	27 AUG 2020 09:27
PC Open Date & Time	27 AUG 2020 09:24
PC Close Date & Time	27 AUG 2020 11:54

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

No

Yes

PC Time stamp	27 AUG 2020 13:10
PC Open Date & Time	27 AUG 2020 12:49
PC Close Date & Time	28 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 12:49
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 12:36
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 12:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 12:03
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 12:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 14:36
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3302395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 SEP 2020

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

Folder OID VISIT2

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:43 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:43
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:30
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3302395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:00 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:00

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

What was the frequency of the study treatment dosing? ONCE

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

US3302395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 24 SEP 2020

Collection time (*00:00-23:59*) 08:46 (24 HR)

Collection date and time (derived) 24 SEP 2020 08:46

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Collection date (<i>dd MMM yyyy</i>)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:44	24 SEP 2020 08:44
Nasopharyngeal Swab 2	Yes	08:44	24 SEP 2020 08:44

US3302395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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 96.8 °F

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

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

PC Time Stamp 24 SEP 2020 09:21

PC Open Date & Time 24 SEP 2020 09:20

PC Close Date & Time 24 SEP 2020 11:50

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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 98.0 °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 24 SEP 2020 13:45
PC Open Date & Time 24 SEP 2020 12:45
PC Close Date & Time 25 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 13:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 SEP 2020 12:17
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 12:01
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 SEP 2020 12:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 12:10
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

24 SEP 2020 09:21

PC Open Date & Time

24 SEP 2020 09:20

PC Close Date & Time

24 SEP 2020 11:50

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

24 SEP 2020 13:46

PC Open Date & Time

24 SEP 2020 12:45

PC Close Date & Time

25 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 2

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	25 SEP 2020 13:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 3

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

26 SEP 2020 12:17

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 4

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	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 5

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	28 SEP 2020 12:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 6

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

29 SEP 2020 12:04

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 7

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	30 SEP 2020 12:10
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

No

Yes

PC Time stamp	24 SEP 2020 09:22
PC Open Date & Time	24 SEP 2020 09:20
PC Close Date & Time	24 SEP 2020 11:50

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

No

Yes

PC Time stamp	24 SEP 2020 13:46
PC Open Date & Time	24 SEP 2020 12:45
PC Close Date & Time	25 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 13:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 12:18
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 12:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 12:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 12:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 12:11
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

01 OCT 2020 13:40

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

03 OCT 2020 12:17

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 13:40
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 12:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 12:17
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3302395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:47 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 07:47
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3302395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3302395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 20 OCT 2020

Collection time (*00:00-23:59*) 08:02 (24 HR)

Collection date and time (derived) 20 OCT 2020 08:02

US3302395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 64

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 27 OCT 2020 00:19:37

Patient Cloud Open Date & Time 27 OCT 2020 00:01

Patient Cloud Close Date & Time 31 OCT 2020 23:59

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 06:15:28
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 10 NOV 2020 05:28:12

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 07:14:59
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 07:25:01
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 05 DEC 2020 07:28:44

Patient Cloud Open Date & Time 05 DEC 2020 00:01

Patient Cloud Close Date & Time 09 DEC 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:11:49
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 19 DEC 2020 07:08:19

Patient Cloud Open Date & Time 19 DEC 2020 00:01

Patient Cloud Close Date & Time 23 DEC 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 05:30:40
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No

Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission 02 JAN 2021 05:23:43

Patient Cloud Open Date & Time 02 JAN 2021 00:01

Patient Cloud Close Date & Time 06 JAN 2021 23:59

US3302395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:02:02

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
---	--	---------------------------

US3302395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 NOV 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:23:43

Generated On: 09 Jun 2021 17:02:02

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 SITE CANCELLED

If Contact Not Made, please provide Comments

US3302395

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:04

Generated On: 09 Jun 2021 17:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3302395

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:02:02

Generate Next COVID-19 Assessment

Yes

No

US3302395

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:58

Generated On: 09 Jun 2021 17:02:02

AEID USA-US087-2021-MRNA-1273-P30
1000013

Adverse event MYOCARDIAL INFARCTION

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 04 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 04 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death True

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:58

Generated On: 09 Jun 2021 17:02:02

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

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:58

Generated On: 09 Jun 2021 17:02:02

SUBJECT SON CALLED SITE TODAY AND REPORTED THAT HIS FATHER HAD PASSED AWAY. SUBJECT WAS FOUND IN HOME ON 1/4/2021 AND WAS DETERMINED THAT HE HAD A MI. THE SON HAS REQUESTED TO UNBLIND AND LET THE FAMILY KNOW IF HE RECEIVED THE VACCINE. EPIP WAS SENT IN. THE SON WILL BRING A COPY OF THE DEATH CERTIFICATE ONCE IT HAS BEEN RECEIVED.

04-MAR-2021 09:15
I TRIED CONTACTING SUBJECTS SON TO OBTAIN A DEATH CERTIFICATE, UNABLE TO LEAVE A MESSAGE. PER VITAL RECORDS OFFICE AT SRMC, FAMILY HAS TO OBTAIN.

24-MAR-2021 15:17
LATE ENTRY: SUBJECT'S SON WAS CONTACTED AND WAS ASKED TO COME TO SITE TO SIGN A MEDICAL RECORD RELEASE FORM. SUBJECT'S SON DECLINED.

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)	

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

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

Yes

No

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

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication NEUROPATHY IN FEET

Dose per administration 800

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

Name of Medication TRAZADONE

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

144 of 1179

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3302395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:42:03

Generated On: 09 Jun 2021 17:02:02

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

Date of study discontinuation/completion (*dd MMM yyyy*) 04 JAN 2021

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify _____

Date of death (*dd MMM yyyy*) 04 JAN 2021

Was autopsy performed?

Yes

No

Unknown

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/JAN/2021 12:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/JAN/2021 15:20
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.	<input checked="" type="checkbox"/> True

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/FEB/2021 15:25
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

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/APR/2021 12:17
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

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 12:46:04

Generated On: 09 Jun 2021 17:02:02

SAEID	USA-US087-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/APR/2021 10:50
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.	<input checked="" type="checkbox"/> True

Audit

US3302395 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302395

Form: Participant Creation

Generated On: 09 Jun 2021 17:02:02

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'SAE has been recorded in EDC stating that subject has passed away. Please complete the End of Study/Study Discontinuation Page as soon as possible.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:07:53
Query 'SAE has been recorded in EDC stating that subject has passed away. Please complete the End of Study/Study Discontinuation Page as soon as possible.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	04 Feb 2021 14:54:25
User opened query 'SAE has been recorded in EDC stating that subject has passed away. Please complete the End of Study/Study Discontinuation Page as soon as possible.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 05:20:08
User entered 'US3302395'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:24:25

US3302395

Form: Participant Creation

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:29

US3302395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:24:26

US3302395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:29

US3302395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'SCRN'	System	27 Aug 2020 12:55:29

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:24:27

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '67'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'YEARS'	System	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '67'	System	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Male (M)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '1'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:36

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'Aug 2020'	System	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '2020'	System	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 14:57:14
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:46

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:24:26

US3302395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '1'	System	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:02:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:01

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensorimotor neuropathy, LLT: Peripheral sensorimotor neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 03:25:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 03:25:04
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) as well as the exact location of Feet (e.g., Right, Left or Bilateral Foot). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:11:37
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral motor neuropathy, LLT: Peripheral motor neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 11:04:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 11:04:18
Data point term sent to Coder	System	09 Oct 2020 14:29:41
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) as well as the exact location of Feet (e.g., Right, Left or Bilateral Foot). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'corrected information' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:28:57
Coding entries removed.	(b) (4), (b) (6)	09 Oct 2020 14:28:44
User entered 'sensorimotor neuropathy in bilateral feet' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 14:28:44

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) as well as the exact location of Feet (e.g., Right, Left or Bilateral Foot). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:44:27
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:30
Data point term sent to Coder	System	27 Aug 2020 12:57:20
User entered 'neuropathy in feet'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'un UNK 2018'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'Jan 2018'	System	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '2018'	System	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered empty.	System	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered empty.	System	27 Aug 2020 12:56:21

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:29
Data point term sent to Coder	System	27 Aug 2020 12:57:20
User entered 'insomnia'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'un UNK 2017'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'Jan 2017'	System	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '2017'	System	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered empty.	System	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered empty.	System	27 Aug 2020 12:56:32

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Please consider entering 08:22 instead of 8:22. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:52:01
Query 'Per CDM: Please consider entering 08:22 instead of 8:22. Thank you!' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	08 Oct 2020 13:45:18
User entered '08:22' reason for change: Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User opened query 'Per CDM: Please consider entering 08:22 instead of 8:22. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:55
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 12:57:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 12:57:12
User entered '8:22' reason for change: Data Entry Error	Brittany Belcher (b) (4)	27 Aug 2020 12:57:12
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 12:57:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 08:22'	System	08 Oct 2020 13:45:12
User entered '27 Aug 2020 8:22'	System	27 Aug 2020 12:57:12
User entered empty.	System	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '74' in	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:57:01
DataPoint set to visible.	System	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '180' lb	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:57:01
DataPoint set to visible.	System	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
Amendment Manager: User entered '23.15895'	System	17 Sep 2020 00:04:48
User entered '23.2'	System	27 Aug 2020 12:57:01
DataPoint set to visible.	System	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'kg/m2'	System	27 Aug 2020 12:57:01
DataPoint set to visible.	System	27 Aug 2020 12:55:50

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:52:02
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	08 Oct 2020 13:45:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 12:57:12
User entered '98' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	27 Aug 2020 12:57:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 12:57:01
User entered '98' (non-conformant).	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User entered '60'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'bpm'	System	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User entered '16'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'breaths/min'	System	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User entered '144'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Oct 2020 13:45:12
User entered '86'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	27 Aug 2020 12:57:01

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24

US3302395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24

US3302395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:18

US3302395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:57:18

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 19:12:57
User entered '1'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 19:12:57
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:57:39

US3302395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:23

US3302395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 13:14:23

US3302395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:23

US3302395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'VISIT1'	System	27 Aug 2020 13:14:23

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:45:01

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '188326'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:45:01

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 12:45:01

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 13:14:15

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:15

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:15

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:15

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:15

US3302395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:15:26
DataPoint set to visible.	System	23 Oct 2020 14:57:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:10:55

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:55:24
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 19:12:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:37
User entered '74' in	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered '180' lb	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:55:24
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 19:12:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:37
User entered '74' in	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered '180' lb	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '08:22' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 08:22'	System	07 Oct 2020 19:12:01
User entered empty.	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '98.0' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '60' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'bpm'	System	07 Oct 2020 19:12:01
User entered empty.	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '16' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'breaths/min'	System	07 Oct 2020 19:12:01
User entered empty.	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '144' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	07 Oct 2020 19:12:01
User entered empty.	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '86' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	07 Oct 2020 19:12:01
User entered empty.	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:55:24
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 19:12:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:18:37
User entered '74' in	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:01
User entered '180' lb	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '09:34' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 19:12:10
User entered '9:34'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 09:34'	System	07 Oct 2020 19:12:10
User entered '27 Aug 2020 9:34'	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '98' F	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '61'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'bpm'	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '18'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'breaths/min'	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '140'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '89'	Brittany Belcher (b) (4)	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'mmHg'	System	27 Aug 2020 17:13:59

US3302395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:03

US3302395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 17:14:03

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '09:04' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:15:34
User entered '9:04'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 09:04'	System	11 Nov 2020 18:15:34
User entered '27 Aug 2020 9:04'	System	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'ONCE'	System	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 13:14:05

US3302395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:13

US3302395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 17:14:13

US3302395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '08:35' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:15:38
User entered '8:35'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:13

US3302395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 08:35'	System	11 Nov 2020 18:15:38
User entered '27 Aug 2020 8:35'	System	27 Aug 2020 17:14:13

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '27 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '08:33' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:15:43
User entered '8:33'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '27 Aug 2020 08:33'	System	11 Nov 2020 18:15:43
User entered '27 Aug 2020 8:33'	System	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 18:14:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 18:14:32
User entered '8:33'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered empty.	System	20 Oct 2020 18:14:32
User entered '27 Aug 2020 8:33'	System	27 Aug 2020 17:14:23

US3302395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 17:14:27

US3302395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '1'	System	27 Aug 2020 17:14:27

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:24:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '82c3fdc7-018e-43e1-8f03-ed0290d12622' User entered 'Yes (Y)'	System	27 Aug 2020 13:25:49
	System	27 Aug 2020 13:25:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:25:29', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '82c3fdc7-018e-43e1-8f03-ed0290d12622' User entered '98.0'	System	27 Aug 2020 13:25:49
	System	27 Aug 2020 13:25:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:25:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '82c3fdc7-018e-43e1-8f03-ed0290d12622'	System	27 Aug 2020 13:25:49
User entered 'No (N)'	System	27 Aug 2020 13:25:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:25:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '82c3fdc7-018e-43e1-8f03-ed0290d12622' User entered '27 Aug 2020 09:25'	System	27 Aug 2020 13:25:49
	System	27 Aug 2020 13:25:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 09:24'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 11:54'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1884ed65-197a-49a7-99e3-60c4087df9e1' User entered 'Yes (Y)'	System	27 Aug 2020 17:09:49
	System	27 Aug 2020 17:09:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1884ed65-197a-49a7-99e3-60c4087df9e1' User entered '98.0'	System	27 Aug 2020 17:09:49
	System	27 Aug 2020 17:09:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1884ed65-197a-49a7-99e3-60c4087df9e1' User entered 'No (N)'	System	27 Aug 2020 17:09:49
	System	27 Aug 2020 17:09:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1884ed65-197a-49a7-99e3-60c4087df9e1' User entered '27 Aug 2020 13:09'	System	27 Aug 2020 17:09:49
	System	27 Aug 2020 17:09:49

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 12:49'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 2'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:46:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8786d970-74c1-48ea-9147-ef83955b11a8' User entered 'Yes (Y)'	System	28 Aug 2020 16:47:36
	System	28 Aug 2020 16:47:36

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:47:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8786d970-74c1-48ea-9147-ef83955b11a8' User entered '97.0'	System	28 Aug 2020 16:47:36
	System	28 Aug 2020 16:47:36

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:47:29', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8786d970-74c1-48ea-9147-ef83955b11a8'	System	28 Aug 2020 16:47:36
User entered 'No (N)'	System	28 Aug 2020 16:47:36

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:47:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8786d970-74c1-48ea-9147-ef83955b11a8' User entered '28 Aug 2020 12:47'	System	28 Aug 2020 16:47:36
	System	28 Aug 2020 16:47:36

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 3'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:34:51', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '90a8e254-c159-4ee0-89df-a702cd48105d' User entered 'Yes (Y)'	System	29 Aug 2020 16:36:00
	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '90a8e254-c159-4ee0-89df-a702cd48105d' User entered '97.6'	System	29 Aug 2020 16:36:00
	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '90a8e254-c159-4ee0-89df-a702cd48105d' User entered 'No (N)'	System	29 Aug 2020 16:36:00
	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '90a8e254-c159-4ee0-89df-a702cd48105d' User entered '29 Aug 2020 12:35'	System	29 Aug 2020 16:36:00
	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 4'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:35', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '208b3a62-49e6-47ab-808f-78fe47de1f66'	System	30 Aug 2020 16:03:53
User entered 'Yes (Y)'	System	30 Aug 2020 16:03:53

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:22', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '208b3a62-49e6-47ab-808f-78fe47de1f66' User entered '97.7'	System	30 Aug 2020 16:03:53
	System	30 Aug 2020 16:03:53

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '208b3a62-49e6-47ab-808f-78fe47de1f66'	System	30 Aug 2020 16:03:53
User entered 'No (N)'	System	30 Aug 2020 16:03:53

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '208b3a62-49e6-47ab-808f-78fe47de1f66'	System	30 Aug 2020 16:03:53
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 16:03:53

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 5'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:02:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd7a29b9-5c2a-47de-aa98-d9f60f4dd10b' User entered 'Yes (Y)'	System	31 Aug 2020 16:03:52
	System	31 Aug 2020 16:03:52

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:02:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd7a29b9-5c2a-47de-aa98-d9f60f4dd10b' User entered '98.0'	System	31 Aug 2020 16:03:52
	System	31 Aug 2020 16:03:52

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:02:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd7a29b9-5c2a-47de-aa98-d9f60f4dd10b' User entered 'No (N)'	System	31 Aug 2020 16:03:52
	System	31 Aug 2020 16:03:52

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:02:48', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd7a29b9-5c2a-47de-aa98-d9f60f4dd10b' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 16:03:52
	System	31 Aug 2020 16:03:52

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 6'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:00:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '58508d51-ff88-40fc-8468-4051f26d5799'	System	01 Sep 2020 16:01:48
User entered 'Yes (Y)'	System	01 Sep 2020 16:01:48

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:00:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '58508d51-ff88-40fc-8468-4051f26d5799' User entered '98.2'	System	01 Sep 2020 16:01:48
	System	01 Sep 2020 16:01:48

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:04', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '58508d51-ff88-40fc-8468-4051f26d5799'	System	01 Sep 2020 16:01:48
User entered 'No (N)'	System	01 Sep 2020 16:01:48

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:08', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '58508d51-ff88-40fc-8468-4051f26d5799'	System	01 Sep 2020 16:01:48
User entered '01 Sep 2020 12:01'	System	01 Sep 2020 16:01:48

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 7'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:34:36', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '4c9c0c0a-35fd-41a6-bde4-24728b6ca05c' User entered 'Yes (Y)'	System	02 Sep 2020 18:35:03
	System	02 Sep 2020 18:35:03

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:34:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '4c9c0c0a-35fd-41a6-bde4-24728b6ca05c' User entered '97.0'	System	02 Sep 2020 18:35:03
	System	02 Sep 2020 18:35:03

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:34:52', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '4c9c0c0a-35fd-41a6-bde4-24728b6ca05c' User entered 'No (N)'	System	02 Sep 2020 18:35:03
	System	02 Sep 2020 18:35:03

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '4c9c0c0a-35fd-41a6-bde4-24728b6ca05c' User entered '02 Sep 2020 14:35'	System	02 Sep 2020 18:35:03
	System	02 Sep 2020 18:35:03

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:26:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c1738bfd-3eef-4d80-a67e-d13f25d172e6'	System	27 Aug 2020 13:27:00
User entered 'None (1)'	System	27 Aug 2020 13:27:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:26:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c1738bfd-3eef-4d80-a67e-d13f25d172e6'	System	27 Aug 2020 13:27:00
User entered 'No (N)'	System	27 Aug 2020 13:27:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:26:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c1738bfd-3eef-4d80-a67e-d13f25d172e6'	System	27 Aug 2020 13:27:00
User entered 'No (N)'	System	27 Aug 2020 13:27:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:26:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c1738bfd-3eef-4d80-a67e-d13f25d172e6'	System	27 Aug 2020 13:27:00
User entered 'None (1)'	System	27 Aug 2020 13:27:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:26:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c1738bfd-3eef-4d80-a67e-d13f25d172e6' User entered '27 Aug 2020 09:26'	System	27 Aug 2020 13:27:00
	System	27 Aug 2020 13:27:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 09:24'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 11:54'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:52', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b06e27b6-344f-416b-b2a5-87de06750722'	System	27 Aug 2020 17:10:15
User entered 'None (1)'	System	27 Aug 2020 17:10:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:09:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b06e27b6-344f-416b-b2a5-87de06750722'	System	27 Aug 2020 17:10:15
User entered 'No (N)'	System	27 Aug 2020 17:10:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:00', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b06e27b6-344f-416b-b2a5-87de06750722'	System	27 Aug 2020 17:10:15
User entered 'No (N)'	System	27 Aug 2020 17:10:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:04', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b06e27b6-344f-416b-b2a5-87de06750722'	System	27 Aug 2020 17:10:15
User entered 'None (1)'	System	27 Aug 2020 17:10:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b06e27b6-344f-416b-b2a5-87de06750722'	System	27 Aug 2020 17:10:15
User entered '27 Aug 2020 13:10'	System	27 Aug 2020 17:10:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 12:49'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 2'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:47:43', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '29a88bb6-e2b4-4cba-a51b-c5a934463ac0' User entered 'None (1)'	System	28 Aug 2020 16:48:20
	System	28 Aug 2020 16:48:20

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:47:50', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '29a88bb6-e2b4-4cba-a51b-c5a934463ac0' User entered 'No (N)'	System	28 Aug 2020 16:48:20
	System	28 Aug 2020 16:48:20

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '29a88bb6-e2b4-4cba-a51b-c5a934463ac0' User entered 'No (N)'	System	28 Aug 2020 16:48:20
	System	28 Aug 2020 16:48:20

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '29a88bb6-e2b4-4cba-a51b-c5a934463ac0' User entered 'None (1)'	System	28 Aug 2020 16:48:20
	System	28 Aug 2020 16:48:20

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '29a88bb6-e2b4-4cba-a51b-c5a934463ac0' User entered '28 Aug 2020 12:48'	System	28 Aug 2020 16:48:20
	System	28 Aug 2020 16:48:20

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 3'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '676121dc-3a1e-4c0b-a585-051dd5ac0e02'	System	29 Aug 2020 16:36:00
User entered 'None (1)'	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:43', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '676121dc-3a1e-4c0b-a585-051dd5ac0e02'	System	29 Aug 2020 16:36:00
User entered 'No (N)'	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '676121dc-3a1e-4c0b-a585-051dd5ac0e02'	System	29 Aug 2020 16:36:00
User entered 'No (N)'	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '676121dc-3a1e-4c0b-a585-051dd5ac0e02'	System	29 Aug 2020 16:36:00
User entered 'None (1)'	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:35:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '676121dc-3a1e-4c0b-a585-051dd5ac0e02' User entered '29 Aug 2020 12:35'	System	29 Aug 2020 16:36:00
	System	29 Aug 2020 16:36:00

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 4'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c6ac04e6-d55c-4f23-be7b-30c85263f71d'	System	30 Aug 2020 16:04:15
User entered 'None (1)'	System	30 Aug 2020 16:04:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:03:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c6ac04e6-d55c-4f23-be7b-30c85263f71d'	System	30 Aug 2020 16:04:15
User entered 'No (N)'	System	30 Aug 2020 16:04:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c6ac04e6-d55c-4f23-be7b-30c85263f71d'	System	30 Aug 2020 16:04:15
User entered 'No (N)'	System	30 Aug 2020 16:04:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:05', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c6ac04e6-d55c-4f23-be7b-30c85263f71d'	System	30 Aug 2020 16:04:15
User entered 'None (1)'	System	30 Aug 2020 16:04:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:11', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c6ac04e6-d55c-4f23-be7b-30c85263f71d' User entered '30 Aug 2020 12:04'	System	30 Aug 2020 16:04:15
	System	30 Aug 2020 16:04:15

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 5'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:02:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c527aaa5-6d9a-436b-b5ce-0a1dbfe1a57c'	System	31 Aug 2020 16:04:18
User entered 'None (1)'	System	31 Aug 2020 16:04:18

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:03', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c527aaa5-6d9a-436b-b5ce-0a1dbfe1a57c' User entered 'No (N)'	System	31 Aug 2020 16:04:18
	System	31 Aug 2020 16:04:18

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:07', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c527aaa5-6d9a-436b-b5ce-0a1dbfe1a57c' User entered 'No (N)'	System	31 Aug 2020 16:04:18
	System	31 Aug 2020 16:04:18

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c527aaa5-6d9a-436b-b5ce-0a1dbfe1a57c'	System	31 Aug 2020 16:04:18
User entered 'None (1)'	System	31 Aug 2020 16:04:18

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:17', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c527aaa5-6d9a-436b-b5ce-0a1dbfe1a57c' User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:04:18
	System	31 Aug 2020 16:04:18

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 6'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '6b7640b6-12c0-48b3-8917-85f18db67f5f'	System	01 Sep 2020 16:02:19
User entered 'None (1)'	System	01 Sep 2020 16:02:19

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '6b7640b6-12c0-48b3-8917-85f18db67f5f' User entered 'No (N)'	System	01 Sep 2020 16:02:19
	System	01 Sep 2020 16:02:19

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:24', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '6b7640b6-12c0-48b3-8917-85f18db67f5f' User entered 'No (N)'	System	01 Sep 2020 16:02:19
	System	01 Sep 2020 16:02:19

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '6b7640b6-12c0-48b3-8917-85f18db67f5f'	System	01 Sep 2020 16:02:19
User entered 'None (1)'	System	01 Sep 2020 16:02:19

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '6b7640b6-12c0-48b3-8917-85f18db67f5f' User entered '01 Sep 2020 12:01'	System	01 Sep 2020 16:02:19
	System	01 Sep 2020 16:02:19

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 7'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:09', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '3a345b2c-bbbe-4fd2-be0f-984f7b646a2d'	System	02 Sep 2020 18:35:29
User entered 'None (1)'	System	02 Sep 2020 18:35:29

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '3a345b2c-bbbe-4fd2-be0f-984f7b646a2d'	System	02 Sep 2020 18:35:29
User entered 'No (N)'	System	02 Sep 2020 18:35:29

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '3a345b2c-bbbe-4fd2-be0f-984f7b646a2d'	System	02 Sep 2020 18:35:29
User entered 'No (N)'	System	02 Sep 2020 18:35:29

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '3a345b2c-bbbe-4fd2-be0f-984f7b646a2d'	System	02 Sep 2020 18:35:29
User entered 'None (1)'	System	02 Sep 2020 18:35:29

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '3a345b2c-bbbe-4fd2-be0f-984f7b646a2d'	System	02 Sep 2020 18:35:29
User entered '02 Sep 2020 14:35'	System	02 Sep 2020 18:35:29

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:07', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:17', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:21', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:24', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered 'None (0)'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:31', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54'	System	27 Aug 2020 13:27:58
User entered 'No (N)'	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T09:27:35', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd301cff3-5dfb-4ff1-aed6-a95a158e6d54' User entered '27 Aug 2020 09:27'	System	27 Aug 2020 13:27:58
	System	27 Aug 2020 13:27:58

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 09:24'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 11:54'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:22', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:25', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:29', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered 'None (0)'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:40', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781'	System	27 Aug 2020 17:10:45
User entered 'No (N)'	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-27T13:10:43', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8d3053db-bcf4-4f7e-ae7d-3613bb6bf781' User entered '27 Aug 2020 13:10'	System	27 Aug 2020 17:10:45
	System	27 Aug 2020 17:10:45

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Aug 2020 12:49'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 2'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:29', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:48', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:52', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'None (0)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:48:59', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered 'No (N)'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-28T12:49:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd341b6d3-23c5-4f4c-b115-425b2a81330b' User entered '28 Aug 2020 12:49'	System	28 Aug 2020 16:49:07
	System	28 Aug 2020 16:49:07

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 3'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:05', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:15', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:27', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'None (0)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered 'No (N)'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-29T12:36:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0d512758-374b-44f6-a98f-a08a34a6a93b' User entered '29 Aug 2020 12:36'	System	29 Aug 2020 16:36:42
	System	29 Aug 2020 16:36:42

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 4'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:21', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:30', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:35', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'None (0)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:48', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered 'No (N)'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-30T12:04:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'edf2b072-1695-4f4a-87aa-29b0c7b4062e' User entered '30 Aug 2020 12:04'	System	30 Aug 2020 16:04:56
	System	30 Aug 2020 16:04:56

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 5'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:45', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'None (0)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:51', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered 'No (N)'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-08-31T12:03:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccd79224-e69d-4e23-977e-aab730854348' User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:07:51
	System	31 Aug 2020 16:07:51

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 6'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:39', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'None (0)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:51', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46' User entered 'None (0)'	System	01 Sep 2020 16:03:12
	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:01:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'None (0)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:02:04', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'None (0)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:02:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'None (0)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:02:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'None (0)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:02:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered 'No (N)'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-01T12:02:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '87bf3d9d-d419-4eaf-9a81-59f39251ec46'	System	01 Sep 2020 16:03:12
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:12

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 7'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90' User entered 'None (0)'	System	02 Sep 2020 18:36:20
	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90' User entered 'None (0)'	System	02 Sep 2020 18:36:20
	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90'	System	02 Sep 2020 18:36:20
User entered 'None (0)'	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:35:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90' User entered 'None (0)'	System	02 Sep 2020 18:36:20
	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:36:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90'	System	02 Sep 2020 18:36:20
User entered 'None (0)'	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:36:07', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90'	System	02 Sep 2020 18:36:20
User entered 'None (0)'	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:36:13', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90'	System	02 Sep 2020 18:36:20
User entered 'No (N)'	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-02T14:36:16', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7d027e85-8535-4299-8be7-9f54b64e7a90' User entered '02 Sep 2020 14:36'	System	02 Sep 2020 18:36:20
	System	02 Sep 2020 18:36:20

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:14:05

US3302395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	03 Sep 2020 20:19:04

US3302395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 20:19:04

US3302395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	03 Sep 2020 20:19:04

US3302395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 20:19:04

US3302395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 20:19:12

US3302395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '1'	System	03 Sep 2020 20:19:12

US3302395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	11 Sep 2020 14:32:25

US3302395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '11 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	11 Sep 2020 14:32:25

US3302395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4) (b) (4)	11 Sep 2020 14:32:25

US3302395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) Wendy Taylor (b) (4)	11 Sep 2020 14:32:25

US3302395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	11 Sep 2020 14:32:28

US3302395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '1'	System	11 Sep 2020 14:32:28

US3302395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	17 Sep 2020 20:47:42

US3302395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '17 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 20:47:42

US3302395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 20:47:42

US3302395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 20:47:42

US3302395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	17 Sep 2020 20:47:44

US3302395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:24
User entered '1'	System	17 Sep 2020 20:47:44

US3302395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 13:04:05

US3302395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	24 Sep 2020 13:04:05

US3302395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	24 Sep 2020 13:04:05

US3302395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'VISIT2'	System	24 Sep 2020 13:04:05

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:51:54
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 18:46:43
User entered '08:43' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 18:46:38
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:34:36
User entered '8:43'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 08:43'	System	15 Oct 2020 18:46:38
User entered '24 Sep 2020 8:43'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '96.8' F	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '81'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'bpm'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '18'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'breaths/min'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '158'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '90'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:51:59
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 18:47:02
User entered '09:30' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 18:46:56
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:34:45
User entered '9:30'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 09:30'	System	15 Oct 2020 18:46:56
User entered '24 Sep 2020 9:30'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '96.8' F	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '81'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'bpm'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '16'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'breaths/min'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '148'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '87'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	24 Sep 2020 14:56:09

US3302395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:14

US3302395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	24 Sep 2020 14:56:14

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '09:00' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:16:02
User entered '9:00'	Brittany Belcher (b) (4)	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 09:00'	System	11 Nov 2020 18:16:02
User entered '24 Sep 2020 9:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4) 	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'ONCE'	System	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 13:04:21

US3302395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:24

US3302395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	24 Sep 2020 14:56:24

US3302395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '08:46' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:16:07
User entered '8:46'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:24

US3302395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 08:46'	System	11 Nov 2020 18:16:07
User entered '24 Sep 2020 8:46'	System	24 Sep 2020 14:56:24

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '24 Sep 2020'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '08:44' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:16:13
User entered '8:44'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 08:44'	System	11 Nov 2020 18:16:13
User entered '24 Sep 2020 8:44'	System	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '08:44' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:16:13
User entered '8:44'	Brittany Belcher (b) (4)	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '24 Sep 2020 08:44'	System	11 Nov 2020 18:16:13
User entered '24 Sep 2020 8:44'	System	24 Sep 2020 14:56:36

US3302395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Sep 2020 14:56:40

US3302395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	24 Sep 2020 14:56:40

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:20:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0482ef4c-6f16-45bd-9543-6067d5d6a941' User entered 'Yes (Y)'	System	24 Sep 2020 13:21:19
	System	24 Sep 2020 13:21:19

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:04', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0482ef4c-6f16-45bd-9543-6067d5d6a941' User entered '96.8'	System	24 Sep 2020 13:21:19
	System	24 Sep 2020 13:21:19

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0482ef4c-6f16-45bd-9543-6067d5d6a941'	System	24 Sep 2020 13:21:19
User entered 'No (N)'	System	24 Sep 2020 13:21:19

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:17', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '0482ef4c-6f16-45bd-9543-6067d5d6a941'	System	24 Sep 2020 13:21:19
User entered '24 Sep 2020 09:21'	System	24 Sep 2020 13:21:19

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 09:20'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 11:50'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:45:35', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7461c3e4-d8b1-4cd8-b333-367e36199302'	System	24 Sep 2020 17:46:00
User entered 'Yes (Y)'	System	24 Sep 2020 17:46:00

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:45:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7461c3e4-d8b1-4cd8-b333-367e36199302' User entered '98.0'	System	24 Sep 2020 17:46:00
	System	24 Sep 2020 17:46:00

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:45:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7461c3e4-d8b1-4cd8-b333-367e36199302'	System	24 Sep 2020 17:46:00
User entered 'No (N)'	System	24 Sep 2020 17:46:00

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:45:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7461c3e4-d8b1-4cd8-b333-367e36199302' User entered '24 Sep 2020 13:45'	System	24 Sep 2020 17:46:00
	System	24 Sep 2020 17:46:00

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 12:45'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 2'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:58:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1767702f-e304-4eba-bbfb-7d1ef423e288'	System	25 Sep 2020 17:59:05
User entered 'Yes (Y)'	System	25 Sep 2020 17:59:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:58:52', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1767702f-e304-4eba-bbfb-7d1ef423e288' User entered '97.1'	System	25 Sep 2020 17:59:05
	System	25 Sep 2020 17:59:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:58:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1767702f-e304-4eba-bbfb-7d1ef423e288'	System	25 Sep 2020 17:59:05
User entered 'No (N)'	System	25 Sep 2020 17:59:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:00', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '1767702f-e304-4eba-bbfb-7d1ef423e288' User entered '25 Sep 2020 13:59'	System	25 Sep 2020 17:59:05
	System	25 Sep 2020 17:59:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 3'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:16:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '75cf1226-6843-4eab-83b1-0ba5af347dbb' User entered 'Yes (Y)'	System	26 Sep 2020 16:17:09
	System	26 Sep 2020 16:17:09

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:16:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '75cf1226-6843-4eab-83b1-0ba5af347dbb' User entered '97.2'	System	26 Sep 2020 16:17:09
	System	26 Sep 2020 16:17:09

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '75cf1226-6843-4eab-83b1-0ba5af347dbb' User entered 'No (N)'	System	26 Sep 2020 16:17:09
	System	26 Sep 2020 16:17:09

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '75cf1226-6843-4eab-83b1-0ba5af347dbb' User entered '26 Sep 2020 12:17'	System	26 Sep 2020 16:17:09
	System	26 Sep 2020 16:17:09

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 4'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:00:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '2a38d824-d0fa-406a-97de-b8a68ba0e544' User entered 'Yes (Y)'	System	27 Sep 2020 16:01:24
	System	27 Sep 2020 16:01:24

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:00:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '2a38d824-d0fa-406a-97de-b8a68ba0e544' User entered '97.0'	System	27 Sep 2020 16:01:24
	System	27 Sep 2020 16:01:24

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:00', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '2a38d824-d0fa-406a-97de-b8a68ba0e544' User entered 'No (N)'	System	27 Sep 2020 16:01:24
	System	27 Sep 2020 16:01:24

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '2a38d824-d0fa-406a-97de-b8a68ba0e544' User entered '27 Sep 2020 12:01'	System	27 Sep 2020 16:01:24
	System	27 Sep 2020 16:01:24

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 5'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:21', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '371c64d8-5380-4d90-86fa-6d4c91a75609' User entered 'Yes (Y)'	System	29 Sep 2020 16:03:56
	System	29 Sep 2020 16:03:56

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '371c64d8-5380-4d90-86fa-6d4c91a75609' User entered '96.8'	System	29 Sep 2020 16:03:56
	System	29 Sep 2020 16:03:56

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '371c64d8-5380-4d90-86fa-6d4c91a75609' User entered 'No (N)'	System	29 Sep 2020 16:03:56
	System	29 Sep 2020 16:03:56

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '371c64d8-5380-4d90-86fa-6d4c91a75609' User entered '28 Sep 2020 12:01'	System	29 Sep 2020 16:03:56
	System	29 Sep 2020 16:03:56

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 6'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:27', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd26290be-2296-4981-bdb8-32f531592d09'	System	29 Sep 2020 16:04:05
User entered 'Yes (Y)'	System	29 Sep 2020 16:04:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd26290be-2296-4981-bdb8-32f531592d09' User entered '97.0'	System	29 Sep 2020 16:04:05
	System	29 Sep 2020 16:04:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd26290be-2296-4981-bdb8-32f531592d09'	System	29 Sep 2020 16:04:05
User entered 'No (N)'	System	29 Sep 2020 16:04:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd26290be-2296-4981-bdb8-32f531592d09' User entered '29 Sep 2020 12:03'	System	29 Sep 2020 16:04:05
	System	29 Sep 2020 16:04:05

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 7'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:13', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e92004ec-5781-4eb4-ad06-15c18739a443' User entered 'Yes (Y)'	System	30 Sep 2020 16:10:34
	System	30 Sep 2020 16:10:34

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:21', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e92004ec-5781-4eb4-ad06-15c18739a443' User entered '97.1'	System	30 Sep 2020 16:10:34
	System	30 Sep 2020 16:10:34

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:24', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e92004ec-5781-4eb4-ad06-15c18739a443' User entered 'No (N)'	System	30 Sep 2020 16:10:34
	System	30 Sep 2020 16:10:34

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e92004ec-5781-4eb4-ad06-15c18739a443' User entered '30 Sep 2020 12:10'	System	30 Sep 2020 16:10:34
	System	30 Sep 2020 16:10:34

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:27', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '447c24d2-5b5d-4202-bb6f-e3c7f6829ad3'	System	24 Sep 2020 13:21:49
User entered 'None (1)'	System	24 Sep 2020 13:21:49

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:31', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '447c24d2-5b5d-4202-bb6f-e3c7f6829ad3'	System	24 Sep 2020 13:21:49
User entered 'No (N)'	System	24 Sep 2020 13:21:49

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '447c24d2-5b5d-4202-bb6f-e3c7f6829ad3' User entered 'No (N)'	System	24 Sep 2020 13:21:49
	System	24 Sep 2020 13:21:49

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '447c24d2-5b5d-4202-bb6f-e3c7f6829ad3'	System	24 Sep 2020 13:21:49
User entered 'None (1)'	System	24 Sep 2020 13:21:49

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:45', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '447c24d2-5b5d-4202-bb6f-e3c7f6829ad3' User entered '24 Sep 2020 09:21'	System	24 Sep 2020 13:21:49
	System	24 Sep 2020 13:21:49

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 09:20'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 11:50'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '43cce1f8-5989-49eb-b818-3dcba92b1b9b'	System	24 Sep 2020 17:46:19
User entered 'None (1)'	System	24 Sep 2020 17:46:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '43cce1f8-5989-49eb-b818-3dcba92b1b9b' User entered 'No (N)'	System	24 Sep 2020 17:46:19
	System	24 Sep 2020 17:46:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '43cce1f8-5989-49eb-b818-3dcba92b1b9b' User entered 'No (N)'	System	24 Sep 2020 17:46:19
	System	24 Sep 2020 17:46:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:13', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '43cce1f8-5989-49eb-b818-3dcba92b1b9b'	System	24 Sep 2020 17:46:19
User entered 'None (1)'	System	24 Sep 2020 17:46:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:16', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '43cce1f8-5989-49eb-b818-3dcba92b1b9b' User entered '24 Sep 2020 13:46'	System	24 Sep 2020 17:46:19
	System	24 Sep 2020 17:46:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 12:45'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 2'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:05', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b5341c00-87df-4c34-a093-a2872eeb8feb' User entered 'None (1)'	System	25 Sep 2020 17:59:24
	System	25 Sep 2020 17:59:24

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b5341c00-87df-4c34-a093-a2872eeb8feb' User entered 'No (N)'	System	25 Sep 2020 17:59:24
	System	25 Sep 2020 17:59:24

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:14', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b5341c00-87df-4c34-a093-a2872eeb8feb' User entered 'No (N)'	System	25 Sep 2020 17:59:24
	System	25 Sep 2020 17:59:24

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:17', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b5341c00-87df-4c34-a093-a2872eeb8feb' User entered 'None (1)'	System	25 Sep 2020 17:59:24
	System	25 Sep 2020 17:59:24

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:21', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b5341c00-87df-4c34-a093-a2872eeb8feb' User entered '25 Sep 2020 13:59'	System	25 Sep 2020 17:59:24
	System	25 Sep 2020 17:59:24

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 3'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '67a49f0a-0058-4eda-b754-70ee449bde0e' User entered 'None (1)'	System	26 Sep 2020 16:17:29
	System	26 Sep 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:15', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '67a49f0a-0058-4eda-b754-70ee449bde0e' User entered 'No (N)'	System	26 Sep 2020 16:17:29
	System	26 Sep 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '67a49f0a-0058-4eda-b754-70ee449bde0e' User entered 'No (N)'	System	26 Sep 2020 16:17:29
	System	26 Sep 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '67a49f0a-0058-4eda-b754-70ee449bde0e' User entered 'None (1)'	System	26 Sep 2020 16:17:29
	System	26 Sep 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:27', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '67a49f0a-0058-4eda-b754-70ee449bde0e' User entered '26 Sep 2020 12:17'	System	26 Sep 2020 16:17:29
	System	26 Sep 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 4'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '10547300-7bc6-4cb0-aec1-e927bbaee60b' User entered 'None (1)'	System	27 Sep 2020 16:01:55
	System	27 Sep 2020 16:01:55

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:16', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '10547300-7bc6-4cb0-aec1-e927bbaee60b' User entered 'No (N)'	System	27 Sep 2020 16:01:55
	System	27 Sep 2020 16:01:55

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '10547300-7bc6-4cb0-aec1-e927bbaee60b' User entered 'No (N)'	System	27 Sep 2020 16:01:55
	System	27 Sep 2020 16:01:55

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:25', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '10547300-7bc6-4cb0-aec1-e927bbaee60b' User entered 'None (1)'	System	27 Sep 2020 16:01:55
	System	27 Sep 2020 16:01:55

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '10547300-7bc6-4cb0-aec1-e927bbaee60b' User entered '27 Sep 2020 12:01'	System	27 Sep 2020 16:01:55
	System	27 Sep 2020 16:01:55

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 5'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '15bbc2db-c65f-45c9-96d8-638ecec3a107'	System	29 Sep 2020 16:03:57
User entered 'None (1)'	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '15bbc2db-c65f-45c9-96d8-638ecec3a107' User entered 'No (N)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:01:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '15bbc2db-c65f-45c9-96d8-638ecec3a107' User entered 'No (N)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '15bbc2db-c65f-45c9-96d8-638ecec3a107'	System	29 Sep 2020 16:03:57
User entered 'None (1)'	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '15bbc2db-c65f-45c9-96d8-638ecec3a107' User entered '28 Sep 2020 12:02'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 6'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7709ca92-f483-412b-83d5-5e8c6f87cb68'	System	29 Sep 2020 16:04:19
User entered 'None (1)'	System	29 Sep 2020 16:04:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:52', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7709ca92-f483-412b-83d5-5e8c6f87cb68'	System	29 Sep 2020 16:04:19
User entered 'No (N)'	System	29 Sep 2020 16:04:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:03:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7709ca92-f483-412b-83d5-5e8c6f87cb68' User entered 'No (N)'	System	29 Sep 2020 16:04:19
	System	29 Sep 2020 16:04:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7709ca92-f483-412b-83d5-5e8c6f87cb68'	System	29 Sep 2020 16:04:19
User entered 'None (1)'	System	29 Sep 2020 16:04:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:05', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '7709ca92-f483-412b-83d5-5e8c6f87cb68'	System	29 Sep 2020 16:04:19
User entered '29 Sep 2020 12:04'	System	29 Sep 2020 16:04:19

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 7'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd615f10-6927-4666-8946-597aa159a89e' User entered 'None (1)'	System	30 Sep 2020 16:10:52
	System	30 Sep 2020 16:10:52

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd615f10-6927-4666-8946-597aa159a89e' User entered 'No (N)'	System	30 Sep 2020 16:10:52
	System	30 Sep 2020 16:10:52

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd615f10-6927-4666-8946-597aa159a89e' User entered 'No (N)'	System	30 Sep 2020 16:10:52
	System	30 Sep 2020 16:10:52

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:45', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd615f10-6927-4666-8946-597aa159a89e' User entered 'None (1)'	System	30 Sep 2020 16:10:52
	System	30 Sep 2020 16:10:52

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:48', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'dd615f10-6927-4666-8946-597aa159a89e' User entered '30 Sep 2020 12:10'	System	30 Sep 2020 16:10:52
	System	30 Sep 2020 16:10:52

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:51', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:56', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:21:59', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:22:02', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:22:04', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'None (0)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:22:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered 'No (N)'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T09:22:15', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd3672f00-4af5-48e5-b6af-55f951661225'	System	24 Sep 2020 13:22:17
User entered '24 Sep 2020 09:22'	System	24 Sep 2020 13:22:17

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 09:20'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 11:50'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:22', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:25', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'None (0)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered 'No (N)'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-24T13:46:47', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e605d617-c178-4c00-91c0-80530a70fa4d' User entered '24 Sep 2020 13:46'	System	24 Sep 2020 17:46:52
	System	24 Sep 2020 17:46:52

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '24 Sep 2020 12:45'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 2'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:27', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:30', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:36', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:39', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'None (0)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:50', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered 'No (N)'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-25T13:59:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'c8761c39-9ef8-42ec-9926-edb2bbd0d22f' User entered '25 Sep 2020 13:59'	System	25 Sep 2020 17:59:57
	System	25 Sep 2020 17:59:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 3'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'None (0)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:17:59', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered 'No (N)'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-26T12:18:03', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'e601d8bb-70a3-4774-8cfc-01d349677b14' User entered '26 Sep 2020 12:18'	System	26 Sep 2020 16:18:05
	System	26 Sep 2020 16:18:05

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 4'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:46', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:50', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:01:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:02:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'None (0)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:02:07', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered 'No (N)'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-27T12:02:11', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f2390e04-9b94-4705-b2a3-527ea62a5b28' User entered '27 Sep 2020 12:02'	System	27 Sep 2020 16:02:37
	System	27 Sep 2020 16:02:37

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 5'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'None (0)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:31', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be'	System	29 Sep 2020 16:03:57
User entered 'Some interference with activity (2)'	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:36', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'None (0)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:39', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'None (0)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'None (0)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:48', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'None (0)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered 'No (N)'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-28T12:02:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '46cb3f55-4cb0-454a-848a-6f092047f2be' User entered '28 Sep 2020 12:02'	System	29 Sep 2020 16:03:57
	System	29 Sep 2020 16:03:57

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 6'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'None (0)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8'	System	29 Sep 2020 16:04:45
User entered 'Some interference with activity (2)'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:23', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'None (0)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'None (0)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:29', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'None (0)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:32', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'None (0)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:38', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered 'No (N)'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-29T12:04:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9c5a7b2-ac4b-44b4-b057-99c5ebec33d8' User entered '29 Sep 2020 12:04'	System	29 Sep 2020 16:04:45
	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	24 Sep 2020 13:04:21
User entered 'Day 7'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'None (0)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:10:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'No interference with activity (1)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'None (0)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:03', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'None (0)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'None (0)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:09', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'None (0)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:13', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered 'No (N)'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-09-30T12:11:16', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '40f0ed50-a591-4805-9c4f-db85b40060a4' User entered '30 Sep 2020 12:11'	System	30 Sep 2020 16:11:18
	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:04:21

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	29 Sep 2020 16:04:45
User entered 'Day 8'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-01T13:40:31', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8cbcb6bf-291e-4ee5-9fc6-13796c7130d8'	System	01 Oct 2020 17:40:39
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-01T13:40:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '8cbcb6bf-291e-4ee5-9fc6-13796c7130d8' User entered '01 Oct 2020 13:40'	System	01 Oct 2020 17:40:39
	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	30 Sep 2020 16:11:18
User entered 'Day 9'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-02T12:00:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccf95132-37cd-42ae-a86c-54424f286faf'	System	02 Oct 2020 16:01:27
User entered 'No interference with activity (1)'	System	02 Oct 2020 16:01:27

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-02T12:01:00', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'ccf95132-37cd-42ae-a86c-54424f286faf' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 16:01:27
	System	02 Oct 2020 16:01:27

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	01 Oct 2020 17:40:39
User entered 'Day 10'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-03T12:17:09', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b9779dfb-397b-4a6c-b8d0-55fd2e2ca810' User entered 'None (0)'	System	03 Oct 2020 16:17:19
	System	03 Oct 2020 16:17:19

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-03T12:17:15', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'b9779dfb-397b-4a6c-b8d0-55fd2e2ca810' User entered '03 Oct 2020 12:17'	System	03 Oct 2020 16:17:19
	System	03 Oct 2020 16:17:19

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	29 Sep 2020 16:04:45
User entered 'Day 8'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-01T13:40:53', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'db669de4-e1f7-48b0-9191-55adb06bde69' User entered 'No (N)'	System	01 Oct 2020 17:41:01
	System	01 Oct 2020 17:41:01

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-01T13:40:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'db669de4-e1f7-48b0-9191-55adb06bde69' User entered '01 Oct 2020 13:40'	System	01 Oct 2020 17:41:01
	System	01 Oct 2020 17:41:01

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:04:45

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	30 Sep 2020 16:11:18
User entered 'Day 9'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-02T12:01:06', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'afda0f00-6650-4307-99b0-135469a1609e' User entered 'No (N)'	System	02 Oct 2020 16:01:42
	System	02 Oct 2020 16:01:42

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-02T12:01:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'afda0f00-6650-4307-99b0-135469a1609e' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 16:01:42
	System	02 Oct 2020 16:01:42

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:11:18

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	01 Oct 2020 17:40:39
User entered 'Day 10'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-03T12:17:22', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f89e06c8-47a7-465b-9124-ee7a7847660d' User entered 'No (N)'	System	03 Oct 2020 16:17:29
	System	03 Oct 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-03T12:17:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'f89e06c8-47a7-465b-9124-ee7a7847660d' User entered '03 Oct 2020 12:17'	System	03 Oct 2020 16:17:29
	System	03 Oct 2020 16:17:29

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:40:39

US3302395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:40:39

US3302395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4) (b) (4)	01 Oct 2020 17:48:13

US3302395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '1 Oct 2020'	(b) (4) Wendy Taylor (b) (4)	01 Oct 2020 17:48:13

US3302395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4) (b) (4)	01 Oct 2020 17:48:13

US3302395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) Wendy Taylor (b) (4)	01 Oct 2020 17:48:13

US3302395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	01 Oct 2020 17:48:17

US3302395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	01 Oct 2020 17:48:17

US3302395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:08:32

US3302395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:08:32

US3302395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:08:32

US3302395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:08:32

US3302395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:08:34

US3302395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	08 Oct 2020 19:08:34

US3302395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:15:08

US3302395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:15:08

US3302395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:15:08

US3302395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:15:08

US3302395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:14:59

US3302395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	15 Oct 2020 17:14:59

US3302395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:21

US3302395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '20 Oct 2020'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:21

US3302395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:21

US3302395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'VISIT3'	System	20 Oct 2020 13:15:21

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '20 Oct 2020'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '07:47'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '20 Oct 2020 07:47'	System	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '97.8' F	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered empty.	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '75'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'bpm'	System	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '16'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'breaths/min'	System	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '148'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '84'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered 'mmHg'	System	20 Oct 2020 13:15:39

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08

US3302395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08

US3302395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:44

US3302395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '20 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	20 Oct 2020 13:15:44

US3302395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:57

US3302395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '20 Oct 2020'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:57

US3302395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered '08:02'	Brittany Belcher (b) (4)	20 Oct 2020 13:15:57

US3302395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '20 Oct 2020 08:02'	System	20 Oct 2020 13:15:57

US3302395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	20 Oct 2020 13:16:01

US3302395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	20 Oct 2020 13:16:01

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 64'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-27T00:19:26', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd28c6930-ec8e-45ce-a36d-df8b163067df'	System	27 Oct 2020 04:19:42
User entered 'No (N)'	System	27 Oct 2020 04:19:42

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-27T00:19:33', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd28c6930-ec8e-45ce-a36d-df8b163067df'	System	27 Oct 2020 04:19:42
User entered 'No (N)'	System	27 Oct 2020 04:19:42

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-10-27T00:19:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd28c6930-ec8e-45ce-a36d-df8b163067df' User entered '27 Oct 2020 00:19:37'	System	27 Oct 2020 04:19:42
	System	27 Oct 2020 04:19:42

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 71'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-03T06:15:18', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d560c08-5c88-4133-af49-06a59b17e1fd'	System	03 Nov 2020 11:15:34
User entered 'No (N)'	System	03 Nov 2020 11:15:34

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-03T06:15:24', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d560c08-5c88-4133-af49-06a59b17e1fd'	System	03 Nov 2020 11:15:34
User entered 'No (N)'	System	03 Nov 2020 11:15:34

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-03T06:15:28', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d560c08-5c88-4133-af49-06a59b17e1fd' User entered '03 Nov 2020 06:15:28'	System	03 Nov 2020 11:15:34
	System	03 Nov 2020 11:15:34

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered 'Day 78'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-10T05:27:58', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d5bd12e-828b-4d0f-81b0-3a8d58045991' User entered 'No (N)'	System	10 Nov 2020 10:28:16
	System	10 Nov 2020 10:28:16

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-10T05:28:08', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d5bd12e-828b-4d0f-81b0-3a8d58045991'	System	10 Nov 2020 10:28:16
User entered 'No (N)'	System	10 Nov 2020 10:28:16

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-10T05:28:12', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d5bd12e-828b-4d0f-81b0-3a8d58045991' User entered '10 Nov 2020 05:28:12'	System	10 Nov 2020 10:28:16
	System	10 Nov 2020 10:28:16

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 13:14:05

US3302395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:47:18
Data entry locked.	System	27 Aug 2020 13:14:05
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 13:14:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-24T07:14:10', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '30a2e4db-2f4e-408c-b9cc-fd36fb440928'	System	24 Nov 2020 12:15:05
User entered 'No (N)'	System	24 Nov 2020 12:15:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-24T07:14:54', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '30a2e4db-2f4e-408c-b9cc-fd36fb440928'	System	24 Nov 2020 12:15:05
User entered 'No (N)'	System	24 Nov 2020 12:15:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-24T07:14:59', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '30a2e4db-2f4e-408c-b9cc-fd36fb440928' User entered '24 Nov 2020 07:14:59'	System	24 Nov 2020 12:15:05
	System	24 Nov 2020 12:15:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-28T07:24:46', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '38ce7eae-a3fa-4db0-adb6-ec592c681e6b'	System	28 Nov 2020 12:25:05
User entered 'No (N)'	System	28 Nov 2020 12:25:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-28T07:24:57', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '38ce7eae-a3fa-4db0-adb6-ec592c681e6b'	System	28 Nov 2020 12:25:05
User entered 'No (N)'	System	28 Nov 2020 12:25:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-11-28T07:25:01', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '38ce7eae-a3fa-4db0-adb6-ec592c681e6b' User entered '28 Nov 2020 07:25:01'	System	28 Nov 2020 12:25:05
	System	28 Nov 2020 12:25:05

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-05T07:28:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '5224dd22-5e1c-41c9-baee-7997f38522f6'	System	05 Dec 2020 12:28:46
User entered 'No (N)'	System	05 Dec 2020 12:28:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-05T07:28:41', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '5224dd22-5e1c-41c9-baee-7997f38522f6'	System	05 Dec 2020 12:28:46
User entered 'No (N)'	System	05 Dec 2020 12:28:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-05T07:28:44', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '5224dd22-5e1c-41c9-baee-7997f38522f6' User entered '05 Dec 2020 07:28:44'	System	05 Dec 2020 12:28:46
	System	05 Dec 2020 12:28:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-12T07:11:42', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'a45f8470-5353-4770-ace1-631aee53e481'	System	12 Dec 2020 12:11:52
User entered 'No (N)'	System	12 Dec 2020 12:11:52

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-12T07:11:45', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'a45f8470-5353-4770-ace1-631aee53e481'	System	12 Dec 2020 12:11:52
User entered 'No (N)'	System	12 Dec 2020 12:11:52

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-12T07:11:49', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'a45f8470-5353-4770-ace1-631aee53e481' User entered '12 Dec 2020 07:11:49'	System	12 Dec 2020 12:11:52
	System	12 Dec 2020 12:11:52

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-19T07:08:11', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9ef6155-2dd0-4044-9fcd-06b8386470a5'	System	19 Dec 2020 12:08:21
User entered 'No (N)'	System	19 Dec 2020 12:08:21

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-19T07:08:15', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9ef6155-2dd0-4044-9fcd-06b8386470a5'	System	19 Dec 2020 12:08:21
User entered 'No (N)'	System	19 Dec 2020 12:08:21

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-19T07:08:19', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: 'd9ef6155-2dd0-4044-9fcd-06b8386470a5' User entered '19 Dec 2020 07:08:19'	System	19 Dec 2020 12:08:21
	System	19 Dec 2020 12:08:21

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-26T05:30:34', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d643768-2f08-469e-9c12-03bdbc55f216'	System	26 Dec 2020 10:30:43
User entered 'No (N)'	System	26 Dec 2020 10:30:43

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-26T05:30:37', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d643768-2f08-469e-9c12-03bdbc55f216'	System	26 Dec 2020 10:30:43
User entered 'No (N)'	System	26 Dec 2020 10:30:43

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2020-12-26T05:30:40', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d643768-2f08-469e-9c12-03bdbc55f216' User entered '26 Dec 2020 05:30:40'	System	26 Dec 2020 10:30:43
	System	26 Dec 2020 10:30:43

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2021-01-02T05:23:36', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d75e22e-17f3-41ba-a3ad-f425e7677cb1'	System	02 Jan 2021 10:23:46
User entered 'No (N)'	System	02 Jan 2021 10:23:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2021-01-02T05:23:39', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d75e22e-17f3-41ba-a3ad-f425e7677cb1'	System	02 Jan 2021 10:23:46
User entered 'No (N)'	System	02 Jan 2021 10:23:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43B618E7-CB4B-4FB3-A35C-B1708EE801D8)', Time: '2021-01-02T05:23:43', User OID: 'PatientReportedOutcome (US3302395)', ODM File OID: '9d75e22e-17f3-41ba-a3ad-f425e7677cb1' User entered '02 Jan 2021 05:23:43'	System	02 Jan 2021 10:23:46
	System	02 Jan 2021 10:23:46

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:42:23

US3302395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:23
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:42:23

US3302395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	18 Nov 2020 15:19:24

US3302395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '18 Nov 2020'	(b) (4) brittany cooksey (b) (4)	18 Nov 2020 15:19:24
	(b) (4)	

US3302395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) brittany cooksey (b) (4)	18 Nov 2020 15:19:24
	(b) (4)	

US3302395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) brittany cooksey (b) (4)	18 Nov 2020 15:19:24
	(b) (4)	

US3302395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4)	18 Nov 2020 15:19:29

US3302395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:08
User entered '1'	System	18 Nov 2020 15:19:29

US3302395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:38:56

US3302395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:38:56

US3302395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:38:56

US3302395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:38:56

US3302395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	22 Dec 2020 17:36:22

US3302395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	22 Dec 2020 17:36:22

US3302395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:43
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	22 Mar 2021 16:17:02
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	10 Mar 2021 15:40:41
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	10 Mar 2021 15:40:41
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	10 Mar 2021 15:40:41
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	10 Mar 2021 15:40:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:39:19

US3302395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:43
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	(b) (4)	10 Mar 2021 15:40:22
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Mar 2021 15:40:22
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	10 Mar 2021 15:40:22
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	04 Feb 2021 14:57:25
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Feb 2021 14:57:25
User entered '21 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 17:39:19

US3302395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	25 Mar 2021 18:23:43
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	22 Mar 2021 16:17:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	29 Jan 2021 17:39:19

US3302395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:43
User entered 'site cancelled'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:39:19

US3302395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:39:28

US3302395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered empty.	System	29 Jan 2021 17:39:28

US3302395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User closed query 'Per CDM Re-query: Response to query is noted. However, per diary dose 2 subject indicated fatigue at day 6-9 (28Sep-02Oct2020), which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:26:49
Query 'Per CDM Re-query: Response to query is noted. However, per diary dose 2 subject indicated fatigue at day 6-9 (28Sep-02Oct2020), which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.' answered with 'Per source, during subject's safety calls 36, 43, and 50 subject denied AE's' (Site from DM).	Brittany Belcher (b) (4)	21 Apr 2021 12:23:10
User opened query 'Per CDM Re-query: Response to query is noted. However, per diary dose 2 subject indicated fatigue at day 6-9 (28Sep-02Oct2020), which lasted beyond day 7 post injection. Please review and verify if these are Solicited Adverse Reaction that should be captured in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 09:38:49
User closed query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 09:38:49

US3302395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'Per source, subject denied any new AE's during Day 36, 43, and 50 safety calls. ' (Site from DM).	Brittany Belcher (b) (4)	19 Apr 2021 16:07:48
User opened query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:52:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:12
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	22 Jan 2021 19:46:54

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:13
User entered 'USA-US087-2021-mRNA-1273-P301000013'	System	25 Jan 2021 17:12:09
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 17:12:09

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:01
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 20:19:23
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 18:26:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	04 Feb 2021 18:26:57
Data point term sent to Coder	System	04 Feb 2021 18:25:27
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' answered with 'updated.' (Site from Safety).	Brittany Belcher (b) (4)	04 Feb 2021 18:24:41
Coding entries removed.	Brittany Belcher (b) (4)	04 Feb 2021 18:24:33
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4)	04 Feb 2021 18:24:33
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 22:59:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 20:00:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	22 Jan 2021 20:00:04
Data point term sent to Coder	System	22 Jan 2021 19:58:50
User entered 'Death'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	04 Feb 2021 18:24:33
User entered 'No (N)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'No (N)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'No (N)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '04 Jan 2021'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered empty.	System	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'No (N)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '04 Jan 2021'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered empty.	System	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 00:14:03
User closed query 'Per source the severity is listed as Grade 5. Kindly review the source, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 00:13:59
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
Query 'Per source the severity is listed as Grade 5. Kindly review the source, and update accordingly.' answered with 'grade 5 is the correct answer/ death, however, this is not an option, please advise.' (Site from CRA).	(b) (4) marsha gossett (b) (4) (b) (4)	04 Mar 2021 14:10:25
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:01
User opened query 'Per source the severity is listed as Grade 5. Kindly review the source, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:15:50
User entered 'Grade 4 (Grade 4)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:01
User closed query 'Per CDM: Subject died on 04Jan2021, however "End of Study/Study Discontinuation" form is not completed. Please consider completing this. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:02:05
Query 'Per CDM: Subject died on 04Jan2021, however "End of Study/Study Discontinuation" form is not completed. Please consider completing this. Thank you!' answered with 'completed. ' (Site from DM).	Brittany Belcher (b) (4)	12 Feb 2021 15:09:36
User opened query 'Per CDM: Subject died on 04Jan2021, however "End of Study/Study Discontinuation" form is not completed. Please consider completing this. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:23:11
User entered '1'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:01
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 07:26:46
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'updated per query' (Site from DM).	brittany cooksey (b) (4)	27 Jan 2021 21:12:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 21:12:41
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:46:09
User entered 'None (NONE)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '1'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered '0'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User closed query 'PV Query: Please amend outcome from Recovered/resolved to Fatal.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 20:19:10
Query 'PV Query: Please amend outcome from Recovered/resolved to Fatal.' answered with 'updated.' (Site from Safety).	Brittany Belcher (b) (4)	04 Feb 2021 18:25:29
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	04 Feb 2021 18:24:33
User opened query 'PV Query: Please amend outcome from Recovered/resolved to Fatal.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:01:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:16:01
User entered empty.	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:45:58
User closed query 'PV URGENT QUERY: PHI has been identified. Please urgently remove from section B.5.1 (case narrative) ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:49:55
Query 'PV URGENT QUERY: PHI has been identified. Please urgently remove from section B.5.1 (case narrative) ' answered with 'updated' (Site from Safety).	Brittany Belcher (b) (4)	06 Apr 2021 17:27:40
DataPoint Un-verified.	Brittany Belcher (b) (4)	06 Apr 2021 17:27:33
Signature has been broken.	Brittany Belcher (b) (4)	06 Apr 2021 17:27:33
User entered 'SUBJECT SON CALLED SITE TODAY AND REPORTED THAT HIS FATHER HAD PASSED AWAY. SUBJECT WAS FOUND IN HOME ON 1/4/2021 AND WAS DETERMINED THAT HE HAD A MI. THE SON HAS REQUESTED TO UNBLIND AND LET THE FAMILY KNOW IF HE RECEIVED THE VACCINE. EPIP WAS SENT IN. THE SON WILL BRING A COPY OF THE DEATH CERTIFICATE ONCE IT HAS BEEN RECEIVED.	Brittany Belcher (b) (4)	06 Apr 2021 17:27:33
<p>04-MAR-2021 09:15 I TRIED CONTACTING SUBJECTS SON TO OBTAIN A DEATH CERTIFICATE, UNABLE TO LEAVE A MESSAGE. PER VITAL RECORDS OFFICE AT SRMC, FAMILY HAS TO OBTAIN.</p>		
<p>24-MAR-2021 15:17 LATE ENTRY: SUBJECT'S SON WAS CONTACTED AND WAS ASKED TO COME TO SITE TO SIGN A MEDICAL RECORD RELEASE FORM. SUBJECT'S SON DECLINED.' reason for change: Data Entry Error</p>		

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV URGENT QUERY: PHI has been identified. Please urgently remove from section B.5.1 (case narrative) ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 17:11:38
DataPoint Verified.	Gregory Feldman (b) (4)	02 Apr 2021 16:05:15
User closed query 'Please add data from Progress Notes in CRIO dated 04Mar2021 and 24Mar2021, so that Monitor can SDV the data.' (Site from CRA). Query 'Please add data from Progress Notes in CRIO dated 04Mar2021 and 24Mar2021, so that Monitor can SDV the data.' answered with 'updated. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 19:20:39
User entered 'SUBJECT SON CALLED SITE TODAY AND REPORTED THAT HIS FATHER HAD PASSED AWAY. SUBJECT WAS FOUND IN HOME ON 1/4/2021 AND WAS DETERMINED THAT HE HAD A MI. THE SON HAS REQUESTED TO UNBLIND AND LET THE FAMILY KNOW IF HE RECEIVED THE VACCINE. EPIP WAS SENT IN. THE SON WILL BRING A COPY OF THE DEATH CERTIFICATE ONCE IT HAS BEEN RECEIVED.	Brittany Belcher (b) (4)	01 Apr 2021 18:05:20
04-MAR-2021 09:15 I TRIED CONTACTING (b) (6) SON TO OBTAIN A DEATH CERTIFICATE, UNABLE TO LEAVE A MESSAGE. PER VITAL RECORDS OFFICE AT SRMC, FAMILY HAS TO OBTAIN.	Brittany Belcher (b) (4)	01 Apr 2021 18:05:02
24-Mar-2021 15:17 Late Entry: Subject's son was contacted and was asked to come to site to sign a medical record release form. Subject's son declined.' reason for change: Data Entry Error Signature has been broken.	Brittany Belcher (b) (4)	01 Apr 2021 18:04:10

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT SON CALLED SITE TODAY AND REPORTED THAT HIS FATHER HAD PASSED AWAY. SUBJECT WAS FOUND IN HOME ON 1/4/2021 AND WAS DETERMINED THAT HE HAD A MI. THE SON HAS REQUESTED TO UNBLIND AND LET THE FAMILY KNOW IF HE RECEIVED THE VACCINE. EPIP WAS SENT IN. THE SON WILL BRING A COPY OF THE DEATH CERTIFICATE ONCE IT HAS BEEN RECEIVED. 04-Mar-2021 09:15 I tried contacting (b) (6) (b) (6) son to obtain a death certificate, unable to leave a message. Per vital records office at SRMC, family has to obtain.' reason for change: Data Entry Error	Brittany Belcher (b) (4)	01 Apr 2021 18:04:10
User opened query 'Please add data from Progress Notes in CRIO dated 04Mar2021 and 24Mar2021, so that Monitor can SDV the data.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 20:08:39
User closed query 'PV Query: Please clarify whether subject had any risk factors for myocardial infarction.' (Site from Safety).	Gregory Feldman (b) (4)	05 Mar 2021 21:45:01
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)	05 Mar 2021 14:51:57
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:51:45
User closed query 'PV Query: It was noted that the subject experienced a MI. Please confirm if this is the cause of death. If so, please update event term to MI, with fatal outcome. If not, please provide cause of death.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:51:38
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:51:21

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'per son, subject was found deceased at home, therefore, no medical intervention was given' (Site from Safety).	marsha gossett (b) (4) (b) (4)	04 Mar 2021 14:08:45
Query 'PV Query: It was noted that the subject experienced a MI. Please confirm if this is the cause of death. If so, please update event term to MI, with fatal outcome. If not, please provide cause of death.' answered with 'this is the information given by the family, site is awaiting information from the coroners office.' (Site from Safety).	marsha gossett (b) (4) (b) (4)	04 Mar 2021 14:08:24
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'site is awaiting information from coroners office. ' (Site from Safety).	marsha gossett (b) (4) (b) (4)	04 Mar 2021 14:08:05
Query 'PV Query: Please clarify whether subject had any risk factors for myocardial infarction.' answered with 'none' (Site from Safety).	marsha gossett (b) (4) (b) (4)	04 Mar 2021 14:07:44
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:17
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:16:01
User opened query 'PV Query: Please clarify whether subject had any risk factors for myocardial infarction.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 23:01:28
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)	01 Feb 2021 23:01:11

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was noted that the subject experienced a MI. Please confirm if this is the cause of death. If so, please update event term to MI, with fatal outcome. If not, please provide cause of death.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 22:59:43
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 22:59:21
User entered 'Subject son called site today and reported that his father had passed away. Subject was found in home on 1/4/2021 and was determined that he had a MI. The son has requested to unblind and let the family know if he received the vaccine. EPIP was sent in. The son will bring a copy of the death certificate once it has been received.'	Wendy Taylor (b) (4)	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	04 Feb 2021 18:24:33
User entered '0'	System	22 Jan 2021 19:58:43

US3302395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:02:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:49:44
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:57:48

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:51:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:22:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:22:51
Data point term sent to Coder	System	27 Aug 2020 12:58:23
User entered 'gabapentin'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
Query 'Per DM CLR: Please update the indication and clarify the type and laterality of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right). Review and update indication and ensure to update MH eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:12:59
User opened query 'Per DM CLR: Please update the indication and clarify the type and laterality of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:15:08
User entered 'neuropathy in feet'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered '800'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'mg (mg)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'three times daily (TID)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '3'	System	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '804 (804)'	System	27 Aug 2020 12:58:18

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:05:42
Data point term sent to Coder	System	27 Aug 2020 12:59:25
User entered 'trazadone'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'insomnia'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered '100'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'mg (mg)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'un UNK 2017'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered '0'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered empty.	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:51:13
User entered 'No (N)'	Brittany Belcher (b) (4)	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '1'	System	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '804 (804)'	System	27 Aug 2020 12:58:41

US3302395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:02:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	27 Aug 2020 12:58:47

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '04 Jan 2021'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System (b) (4)	04 Feb 2021 14:59:44
User entered 'Death (DEATH)' reason for change: Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 14:59:44
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	04 Feb 2021 14:57:25
User entered 'SAE (specify) (SAE)'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

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)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	17 Mar 2021 20:15:47
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	17 Mar 2021 20:15:47
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	17 Mar 2021 20:15:33
Signature has been broken.	Brittany Belcher (b) (4)	17 Mar 2021 20:15:33
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4)	17 Mar 2021 20:15:33
User closed query 'Per CDM: Please consider adding here AE with number instead of marking "Unknown" because AE is entered with "Death". Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 17:34:07
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	19 Feb 2021 17:34:07
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 17:33:43

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 17:33:43
User entered 'MYOCARDIAL INFARCTION' reason for change: Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	19 Feb 2021 17:33:43
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 15:44:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 15:44:52
User entered 'MYOCARDIAL INFARCTION (AE #1)' reason for change: Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	19 Feb 2021 15:44:52
Query 'Per CDM: Please consider adding here AE with number instead of marking "Unknown" because AE is entered with "Death". Thank you!' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4) [REDACTED]	19 Feb 2021 15:43:31
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 15:43:23
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	19 Feb 2021 15:43:23
User opened query 'Per CDM: Please consider adding here AE with number instead of marking "Unknown" because AE is entered with "Death". Thank you!' (Site from DM).	(b) (4), (b) (6) [REDACTED]	15 Feb 2021 06:01:56

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	04 Feb 2021 15:00:10
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:00:10
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	04 Feb 2021 14:59:44
User entered 'Death'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 18:55:26
User closed query 'Per CDM re-query: Thank you. Please add here AE#1 instead of writing here "Adverse Event". Thank you!' (Site from DM).	System	06 Apr 2021 18:55:26
User closed query 'Per CDM re-query: Thank you. Please add here AE#1 instead of writing here "Adverse Event". Thank you!' answered with 'We don't have the option to write "AE #1" in this space other than writing in this response box to this query. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:29:32
User opened query 'Per CDM re-query: Thank you. Please add here AE#1 instead of writing here "Adverse Event". Thank you!'.	Brittany Belcher (b) (4)	01 Apr 2021 14:31:17
User opened query 'Per CDM re-query: Thank you. Please add here AE#1 instead of writing here "Adverse Event". Thank you!'.	(b) (4), (b) (6)	25 Mar 2021 05:41:13
User closed query 'Per CDM re-query: Please be aware that nothing is updated. Please add AE#1 instead of Adverse Event. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:41:13
Query 'Per CDM re-query: Please be aware that nothing is updated. Please add AE#1 instead of Adverse Event. Thank you!' answered with 'AE #1 Myocardial Infarction) is listed. ' (Site from DM).	Brittany Belcher (b) (4)	24 Mar 2021 20:59:13
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	24 Mar 2021 20:58:17
User closed query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	24 Mar 2021 20:58:17
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 20:58:17
User opened query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	24 Mar 2021 18:23:02
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 18:23:02

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Please be aware that nothing is updated. Please add AE#1 instead of Adverse Event. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:10:55
User closed query 'Per CDM re-query: Thank you for your answer. Please add here AE#1 instead of Adverse Event. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:10:55
Query 'Per CDM re-query: Thank you for your answer. Please add here AE#1 instead of Adverse Event. Thank you!' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	22 Mar 2021 14:09:03
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	22 Mar 2021 14:08:47
User opened query 'Per CDM re-query: Thank you for your answer. Please add here AE#1 instead of Adverse Event. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:13
User closed query 'Per CDM: It is marked here "Unknown", however AE states that subject died because of myocardial infarction. Please consider adding here AE#1 instead of unknown. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:13
Query 'Per CDM: It is marked here "Unknown", however AE states that subject died because of myocardial infarction. Please consider adding here AE#1 instead of unknown. Thank you!' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	04 Mar 2021 21:23:30
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	04 Mar 2021 21:23:23
Signature has been broken.	Brittany Belcher (b) (4)	04 Mar 2021 21:23:23
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	04 Mar 2021 21:23:23
User opened query 'Per CDM: It is marked here "Unknown", however AE states that subject died because of myocardial infarction. Please consider adding here AE#1 instead of unknown. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:16:27

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25
	(b) (4)	

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User entered empty; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Apr 2021 18:55:26
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 18:23:02
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	22 Mar 2021 14:08:47
Signature has been broken.	Brittany Belcher (b) (4)	04 Mar 2021 21:23:23
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4)	04 Mar 2021 21:23:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered empty.	(b) (4) brittany cooksey (b) (4)	04 Feb 2021 14:57:25
	(b) (4)	

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '04 Jan 2021'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25

US3302395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:02

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered 'Unknown (UNK)'	brittany cooksey (b) (4)	04 Feb 2021 14:57:25

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
User entered '25/Jan/2021 12:12'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:02

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)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
User entered '28/Jan/2021 15:20'	System	28 Jan 2021 15:20:34

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:02

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)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 20:25:15
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 15:20:34

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
User entered '05/Feb/2021 15:25'	System	05 Feb 2021 20:25:58

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:02

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)	28 Apr 2021 15:04:14
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:17:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 20:25:58

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User entered '02/Apr/2021 12:17'	(b) (4) System	02 Apr 2021 16:17:20

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:02

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)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:17:30
User entered '1'	(b) (4), (b) (6)	02 Apr 2021 16:17:20

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'USA-US087-2021-MRNA-1273-P301000013'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Yes (Y)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'No (N)'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Gregory'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Feldman'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '141 Harold Fleming Court'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered 'Spartanburg'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 17:12:20
User entered '29303'	System	25 Jan 2021 17:12:09

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:05:03
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 15:20:24
User entered 'US'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User entered '5'	System	07 Apr 2021 14:50:29
User entered '4'	System	02 Apr 2021 16:17:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:42:05
User entered '3'	System	05 Feb 2021 20:25:58
User entered '2'	System	28 Jan 2021 15:20:34
User entered '1'	System	25 Jan 2021 17:12:27

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User entered '07/Apr/2021 10:50'	(b) (4) System	07 Apr 2021 14:50:29

US3302395

Folder: SAE USA-US087-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:02

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)	28 Apr 2021 15:04:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:46:04
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 14:50:29