

US3302465 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3302465

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

[Participant ID](#)

US3302465

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

US3302465

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3302465

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:35:16

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Date of Informed Consent (*dd MMM yyyy*) 29 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3302465

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:35:16

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:35:16

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 20:35:16

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Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Condition	BENIGN PROSTATE HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Condition	POLYURIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 29 SEP 2020

Time of assessment (*00:00-23:59*) 14:28 (24 HR)

Vital Signs Date and Time (derived) 29 SEP 2020 14:28

Height (*xxx.x*) 70.5 in

Weight (*xxx.x*) 205 lb

BMI (*xxx.x*) 29.05932 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) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

29 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:35:16

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:35:16

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 20:35:17

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What was the date of randomization? (dd MMM yyyy) 29 SEP 2020

What was the participant's randomization number? 191287

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk
 >=18 and <65 years and at risk
 >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes No

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes No

Severe obesity (body mass index > or = 40kg/m2) Yes No

Diabetes (Type I, Type 2, or gestational) Yes No

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:28 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:28
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:36 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:36
Temperature (<i>xxx.x</i>)	98.6 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>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 15:06 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 15:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 29 SEP 2020

Collection time (*00:00-23:59*) 14:54 (24 HR)

Collection date and time (derived) 29 SEP 2020 14:54

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Collection date (<i>dd MMM yyyy</i>)			29 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	14:52	29 SEP 2020 14:52
Nasopharyngeal Swab 2	No		

US3302465

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 98.6 °F

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

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

PC Time Stamp 29 SEP 2020 15:29

PC Open Date & Time 29 SEP 2020 15:26

PC Close Date & Time 29 SEP 2020 17:56

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 SEP 2020 18:51

PC Close Date & Time

30 SEP 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

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	98.6 °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	30 SEP 2020 17:37
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 01 OCT 2020 18:06

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

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	98.6 °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	02 OCT 2020 17:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.4 °F

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

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

PC Time Stamp 03 OCT 2020 17:49

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

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	04 OCT 2020 20:54
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

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	98.6 °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	05 OCT 2020 17:22
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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	29 SEP 2020 15:31
PC Open Date & Time	29 SEP 2020 15:26
PC Close Date & Time	29 SEP 2020 17:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

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

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

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

- Yes
- No

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

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

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

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

PC Open Date & Time

29 SEP 2020 18:51

PC Close Date & Time

30 SEP 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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	30 SEP 2020 17:38
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

100

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

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 OCT 2020 18:08
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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	02 OCT 2020 17:07
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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	03 OCT 2020 17:50
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

04 OCT 2020 20:56

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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	05 OCT 2020 17:23
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

No

Yes

PC Time stamp	29 SEP 2020 15:32
PC Open Date & Time	29 SEP 2020 15:26
PC Close Date & Time	29 SEP 2020 17:56

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

No

Yes

PC Time stamp

PC Open Date & Time

29 SEP 2020 18:51

PC Close Date & Time

30 SEP 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 17:39
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 18:10
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 17:09
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	03 OCT 2020 17:51
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 20:57
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	05 OCT 2020 17:24
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3302465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT2

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:58 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 09:58
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 11:10
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3302465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 10:40

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

US3302465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:08 (24 HR)
Collection date and time (derived)	27 OCT 2020 10:08

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Collection date (<i>dd MMM yyyy</i>)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	27 OCT 2020 10:05
Nasopharyngeal Swab 2	Yes	10:05	27 OCT 2020 10:05

US3302465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp 27 OCT 2020 11:08

PC Open Date & Time 27 OCT 2020 11:00

PC Close Date & Time 27 OCT 2020 13:30

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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** 98.3 °F

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

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

PC Time Stamp 28 OCT 2020 01:14
PC Open Date & Time 27 OCT 2020 14:25
PC Close Date & Time 28 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 OCT 2020 12:04

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

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	98.5 °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 OCT 2020 12:03
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 30 OCT 2020 19:48

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp 31 OCT 2020 14:23

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

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	98.6 °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	01 NOV 2020 17:10
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

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	98.5 °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 NOV 2020 12:08
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020 11:09

PC Open Date & Time

27 OCT 2020 11:00

PC Close Date & Time

27 OCT 2020 13:30

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

28 OCT 2020 01:14

PC Open Date & Time

27 OCT 2020 14:25

PC Close Date & Time

28 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

6

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

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 OCT 2020 12:14
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

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

5

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

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

- Yes
- No

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

6

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

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 OCT 2020 12:07

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020 19:50

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 OCT 2020 14:24

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 NOV 2020 17:12

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 NOV 2020 12:09

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

No

Yes

PC Time stamp	27 OCT 2020 11:09
PC Open Date & Time	27 OCT 2020 11:00
PC Close Date & Time	27 OCT 2020 13:30

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

No
Yes

PC Time stamp	28 OCT 2020 01:15
PC Open Date & Time	27 OCT 2020 14:25
PC Close Date & Time	28 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	28 OCT 2020 12:16
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	29 OCT 2020 12:08
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	30 OCT 2020 19:51
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	31 OCT 2020 14:25
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	01 NOV 2020 17:13
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

	Yes <input type="checkbox"/>
PC Time stamp	02 NOV 2020 12:09
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3302465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3302465

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 NOV 2020

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

Folder OID VISIT3

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 23 NOV 2020

Time of assessment (00:00-23:59) 10:37 (24 HR)

Vital Signs Date and Time (derived) 23 NOV 2020 10:37

Temperature (xxx.x) 97.7 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 82 beats/min

Pulse units BPM

Respiratory Rate (xxx) 18 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 149 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 88 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3302465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3302465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 NOV 2020

Collection time (*00:00-23:59*) 10:40 (24 HR)

Collection date and time (derived) 23 NOV 2020 10:40

US3302465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:17

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

DAY 61

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 30 NOV 2020 14:08:01

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT	DAY 68
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 DEC 2020 10:54:04
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT	DAY 75
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	11 DEC 2020 12:39:55
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT	DAY 82
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	17 DEC 2020 10:41:55
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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

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 24 DEC 2020 12:04:20

Patient Cloud Open Date & Time 24 DEC 2020 00:01

Patient Cloud Close Date & Time 28 DEC 2020 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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	31 DEC 2020 12:48:55
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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 07 JAN 2021 08:12:51

Patient Cloud Open Date & Time 07 JAN 2021 00:01

Patient Cloud Close Date & Time 11 JAN 2021 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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	14 JAN 2021 12:58:05
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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 <input 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 type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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	29 JAN 2021 14:12:43
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3302465

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:03:38

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
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US3302465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

Was Contact Attempted? Yes
No

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

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

Comments _____

If Contact Not Made, please provide Comments _____

US3302465

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3302465

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:03:38

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"/>

US3302465

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:03:38

Generate Next COVID-19 Assessment

Yes

No

US3302465

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3302465

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:38:54

Generated On: 09 Jun 2021 17:03:38

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

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

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3302465

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 JAN 2021
Collection time (<i>00:00-23:59</i>)	13:02 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:02

US3302465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:35:15

Generated On: 09 Jun 2021 17:03:38

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 JAN 2021

Collection time (*00:00 - 23:59*) 13:00

Collection Date and Time (derived) 12 JAN 2021 13:00

US3302465

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

AEID USA-US087-2021-MRNA-1273-P30
1000012

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) 29 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) 29 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

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

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

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

3/19/2021 UPDATE: SITE HAS REACHED OUT TO FAMILY SEVERAL TIMES AND HAVE BEEN UNABLE TO OBTAIN ANY FURTHER INFORMATION. SUBJECTS NIECE STATES THEY ARE NOT POWER OF ATTORNEY AND CANNOT SIGN A RELEASE TO OBTAIN MEDICAL RECORDS. PER THE VITAL RECORDS DEPT AT SRMC, ONLY AUTHORIZED FAMILY MEMBERS CAN OBTAIN A DEATH CERTIFICATE.

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)	

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:35:15

Generated On: 09 Jun 2021 17:03:38

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

Yes

No

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

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

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)

143 of 1316

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

	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 2015

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

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication GLIPIZIDE

Prophylaxis Yes
No

Indication DIABETES MELLITUS TYPE 2

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

	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 2015

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication TAMULOSIN

Prophylaxis Yes
No

Indication BPH

Dose per administration 0.4

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)

147 of 1316

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

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 2014

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

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication FESOTERODINE

Prophylaxis Yes
No

Indication POLYURIA

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

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 2015

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

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication INJECTION PAIN

Dose per administration 500

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

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

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*) 01 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication INJECTION PAIN

Dose per administration 500

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)

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US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 20:35:14

Generated On: 09 Jun 2021 17:03:38

	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*) 28 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 28 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3302465

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:35:15

Generated On: 09 Jun 2021 17:03:38

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 25 Mar 2021 18:26:57

Generated On: 09 Jun 2021 17:03:38

Date of study discontinuation/completion (*dd MMM yyyy*) 29 JAN 2021

Reason for discontinuation

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

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	<input checked="" type="radio"/>
Unknown	<input type="radio"/>
Other	<input type="radio"/>

If main cause of death is Other, specify _____

Date of death (*dd MMM yyyy*) 29 JAN 2021

Was autopsy performed?

Yes	<input type="radio"/>
No	<input type="radio"/>
Unknown	<input checked="" type="radio"/>

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000012
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)	3

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000012
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)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 15:07
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

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000012
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)	3
Date of submission (Pre-filled from custom function)	03/MAR/2021 13:12
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

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 16:08:42

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000012
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)	3
Date of submission (Pre-filled from custom function)	02/APR/2021 09:57
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

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000016
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)	1

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 20:35:16

Generated On: 09 Jun 2021 17:03:38

SAEID	USA-US087-2021-MRNA-1273-P301000016
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)	1
Date of submission (Pre-filled from custom function)	01/FEB/2021 19:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3302465 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302465

Form: Participant Creation

Generated On: 09 Jun 2021 17:03:38

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'US3302465'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 18:07:49

US3302465

Form: Participant Creation

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:16

US3302465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 18:07:50

US3302465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:16

US3302465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'SCRN'	System	29 Sep 2020 19:07:16

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 18:07:52

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '69'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'YEARS'	System	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '69'	System	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Male (M)'	Brittany Belcher (b) (4) 	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '1'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:27

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Sep 2020'	System	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2020'	System	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 16:23:44
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:37

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 18:07:50

US3302465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '1'	System	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:03:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:17

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:01:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:01:37
Data point term sent to Coder	System	29 Sep 2020 20:00:56
User entered 'diabetes mellitus type 2'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2012'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2012'	System	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2012'	System	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:00:35

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:01:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:01:37
Data point term sent to Coder	System	29 Sep 2020 20:00:57
User entered 'hypertension'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2012'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2012'	System	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2012'	System	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:00:48

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
Data point term sent to Coder	System	29 Sep 2020 20:01:59
User entered 'benign prostate hyperplasia'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2014'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2014'	System	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2014'	System	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:12

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Polyuria, LLT: Polyuria - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
Data point term sent to Coder	System	29 Sep 2020 20:01:59
User entered 'polyuria'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2015'	System	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2015'	System	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:24

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 10:32:41
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Subject reports to not taking any medication for this condition. ' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 16:21:16
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:17:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:02:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:02:37
Data point term sent to Coder	System	29 Sep 2020 20:01:59
User entered 'copd'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2007'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2007'	System	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2007'	System	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	29 Sep 2020 20:01:35

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 20:02:37
Data point term sent to Coder	System	29 Sep 2020 20:01:59
User entered 'prostate cancer'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2016'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'un UNK 2016'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2016'	System	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2016'	System	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'Jan 2016'	System	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '2016'	System	29 Sep 2020 20:01:55

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '14:28'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '29 Sep 2020 14:28'	System	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '70.5' in	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:02:38
DataPoint set to visible.	System	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '205' lb	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:02:38
DataPoint set to visible.	System	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '29.05932'	System	29 Sep 2020 20:02:38
DataPoint set to visible.	System	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'kg/m2'	System	29 Sep 2020 20:02:38
DataPoint set to visible.	System	29 Sep 2020 19:07:41

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 13:39:20
	(b) (4)	
User entered '98.4' F	Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:20
User entered 'Oral (Oral)'	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:39:20
User entered '68'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'bpm'	System	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:39:20
User entered '18'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'breaths/min'	System	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:39:20
User entered '134'	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'mmHg'	System	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:39:20
User entered '70'	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered 'mmHg'	System	29 Sep 2020 20:02:38

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45

US3302465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45

US3302465

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:02:43

US3302465

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:02:43

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

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[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4) 	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

[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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '1'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 19:08:53

US3302465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:01

US3302465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:01

US3302465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[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 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:01

US3302465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'VISIT1'	System	29 Sep 2020 19:09:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 19:03:00

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '191287'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 19:03:00

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 19:03:00

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:22

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:22

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:22

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:22

US3302465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:16:20
Query 'Per CDM: This field requires a Yes or No response. Please complete. answered with 'done' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 13:20:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Dec 2020 13:20:16
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:14:45
Data hard unlocked.	(b) (4), (b) (6)	02 Dec 2020 20:14:36
Data hard locked.	(b) (4), (b) (6)	02 Dec 2020 20:14:33
DataPoint set to visible.	System	23 Oct 2020 16:23:44

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered 'No (N)'	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '14:28' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '29 Sep 2020 14:28'	System	05 Oct 2020 13:39:04
User entered empty.	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Other (Other)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:39:04
User entered empty.	Brittany Belcher (b) (4) [Redacted] [Redacted]	29 Sep 2020 20:05:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '68' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'bpm'	System	05 Oct 2020 13:39:04
User entered empty.	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '18' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'breaths/min'	System	05 Oct 2020 13:39:04
User entered empty.	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '134' reason for change: Data Entry Error	(b) (4) brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'mmHg'	System	05 Oct 2020 13:39:04
User entered empty.	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '70' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 13:39:04
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'mmHg'	System	05 Oct 2020 13:39:04
User entered empty.	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 13:36:48
User entered empty.	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '15:36'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '29 Sep 2020 15:36'	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '98.6' F	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '60'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'bpm'	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '18'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'breaths/min'	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '136'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'mmHg'	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '68'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'mmHg'	System	29 Sep 2020 20:05:17

US3302465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	29 Sep 2020 20:05:21

US3302465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:05:21

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '15:06'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '29 Sep 2020 15:06'	System	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'ONCE'	System	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 19:09:38

US3302465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:30

US3302465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:05:30

US3302465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '14:54'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:30

US3302465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '29 Sep 2020 14:54'	System	29 Sep 2020 20:05:30

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '14:52'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '29 Sep 2020 14:52'	System	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:39:46
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:39:46
User entered '14:52'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered empty.	System	20 Oct 2020 17:39:46
User entered '29 Sep 2020 14:52'	System	29 Sep 2020 20:05:41

US3302465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:05:47

US3302465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '1'	System	29 Sep 2020 20:05:47

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:28:37', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '47316964-dc3f-45e1-a3da-07e526d347b7' User entered 'Yes (Y)'	System	29 Sep 2020 19:29:43
	System	29 Sep 2020 19:29:43

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:29:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '47316964-dc3f-45e1-a3da-07e526d347b7'	System	29 Sep 2020 19:29:43
User entered '98.6'	System	29 Sep 2020 19:29:43

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:29:12', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '47316964-dc3f-45e1-a3da-07e526d347b7'	System	29 Sep 2020 19:29:43
User entered 'No (N)'	System	29 Sep 2020 19:29:43

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:29:37', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '47316964-dc3f-45e1-a3da-07e526d347b7' User entered '29 Sep 2020 15:29'	System	29 Sep 2020 19:29:43
	System	29 Sep 2020 19:29:43

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 15:26'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 17:56'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 18:51'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 2'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:36:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'df663ae5-9209-4d6f-a9f5-09ff321b4aeb' User entered 'Yes (Y)'	System	30 Sep 2020 21:37:40
	System	30 Sep 2020 21:37:40

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:37:06', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'df663ae5-9209-4d6f-a9f5-09ff321b4aeb' User entered '98.6'	System	30 Sep 2020 21:37:40
	System	30 Sep 2020 21:37:40

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:37:15', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'df663ae5-9209-4d6f-a9f5-09ff321b4aeb'	System	30 Sep 2020 21:37:40
User entered 'No (N)'	System	30 Sep 2020 21:37:40

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:37:36', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'df663ae5-9209-4d6f-a9f5-09ff321b4aeb' User entered '30 Sep 2020 17:37'	System	30 Sep 2020 21:37:40
	System	30 Sep 2020 21:37:40

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 3'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:04:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9' User entered 'Yes (Y)'	System	01 Oct 2020 22:06:23
	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:04:59', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9'	System	01 Oct 2020 22:06:23
User entered '98.5'	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:05:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9'	System	01 Oct 2020 22:06:23
User entered 'Yes (Y)'	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:05:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9'	System	01 Oct 2020 22:06:23
User entered '0'	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 15:13:45
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	Brittany Belcher (b) (4)	28 Oct 2020 18:55:22
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 22:06:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:05:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9'	System	01 Oct 2020 22:06:23
User entered '1'	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:06:21', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '069d6605-73f0-44a0-bc54-fe6c9ff9c8b9' User entered '01 Oct 2020 18:06'	System	01 Oct 2020 22:06:23
	System	01 Oct 2020 22:06:23

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 4'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:05:40', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'ddc5c547-0849-4f77-90e1-75bce4f8ef43'	System	02 Oct 2020 21:06:39
User entered 'Yes (Y)'	System	02 Oct 2020 21:06:39

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:06:12', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'ddc5c547-0849-4f77-90e1-75bce4f8ef43'	System	02 Oct 2020 21:06:39
User entered '98.6'	System	02 Oct 2020 21:06:39

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:06:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'ddc5c547-0849-4f77-90e1-75bce4f8ef43'	System	02 Oct 2020 21:06:39
User entered 'No (N)'	System	02 Oct 2020 21:06:39

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:06:35', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'ddc5c547-0849-4f77-90e1-75bce4f8ef43'	System	02 Oct 2020 21:06:39
User entered '02 Oct 2020 17:06'	System	02 Oct 2020 21:06:39

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 5'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:48:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c48c74bc-5e35-4ec1-92be-5faf0ae49a27'	System	03 Oct 2020 21:49:29
User entered 'Yes (Y)'	System	03 Oct 2020 21:49:29

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:49:13', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c48c74bc-5e35-4ec1-92be-5faf0ae49a27'	System	03 Oct 2020 21:49:29
User entered '98.4'	System	03 Oct 2020 21:49:29

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:49:23', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c48c74bc-5e35-4ec1-92be-5faf0ae49a27'	System	03 Oct 2020 21:49:29
User entered 'No (N)'	System	03 Oct 2020 21:49:29

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:49:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c48c74bc-5e35-4ec1-92be-5faf0ae49a27'	System	03 Oct 2020 21:49:29
User entered '03 Oct 2020 17:49'	System	03 Oct 2020 21:49:29

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 6'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:54:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '0f7a6d99-eef2-4ac9-8587-36903070018f' User entered 'Yes (Y)'	System	05 Oct 2020 00:54:57
	System	05 Oct 2020 00:54:57

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:54:36', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '0f7a6d99-eef2-4ac9-8587-36903070018f' User entered '98.2'	System	05 Oct 2020 00:54:57
	System	05 Oct 2020 00:54:57

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:54:51', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '0f7a6d99-eef2-4ac9-8587-36903070018f' User entered 'No (N)'	System	05 Oct 2020 00:54:57
	System	05 Oct 2020 00:54:57

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:54:56', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '0f7a6d99-eef2-4ac9-8587-36903070018f' User entered '04 Oct 2020 20:54'	System	05 Oct 2020 00:54:57
	System	05 Oct 2020 00:54:57

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 7'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:21:47', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7533fad2-069e-47c2-877d-98dd41571aab' User entered 'Yes (Y)'	System	05 Oct 2020 21:22:30
	System	05 Oct 2020 21:22:30

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:22:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7533fad2-069e-47c2-877d-98dd41571aab' User entered '98.6'	System	05 Oct 2020 21:22:30
	System	05 Oct 2020 21:22:30

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:22:14', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7533fad2-069e-47c2-877d-98dd41571aab'	System	05 Oct 2020 21:22:30
User entered 'No (N)'	System	05 Oct 2020 21:22:30

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:22:26', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7533fad2-069e-47c2-877d-98dd41571aab' User entered '05 Oct 2020 17:22'	System	05 Oct 2020 21:22:30
	System	05 Oct 2020 21:22:30

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:30:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5024e61e-95a7-4ddf-814b-7710fde31f31'	System	29 Sep 2020 19:31:10
User entered 'None (1)'	System	29 Sep 2020 19:31:10

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:30:46', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5024e61e-95a7-4ddf-814b-7710fde31f31'	System	29 Sep 2020 19:31:10
User entered 'No (N)'	System	29 Sep 2020 19:31:10

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:30:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5024e61e-95a7-4ddf-814b-7710fde31f31'	System	29 Sep 2020 19:31:10
User entered 'No (N)'	System	29 Sep 2020 19:31:10

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5024e61e-95a7-4ddf-814b-7710fde31f31'	System	29 Sep 2020 19:31:10
User entered 'None (1)'	System	29 Sep 2020 19:31:10

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:08', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5024e61e-95a7-4ddf-814b-7710fde31f31'	System	29 Sep 2020 19:31:10
User entered '29 Sep 2020 15:31'	System	29 Sep 2020 19:31:10

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 15:26'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 17:56'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 18:51'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 2'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:37:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '487287c5-f5b8-4575-9afe-c44629c73cde'	System	30 Sep 2020 21:38:27
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 21:38:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:05', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '487287c5-f5b8-4575-9afe-c44629c73cde' User entered 'No (N)'	System	30 Sep 2020 21:38:27
	System	30 Sep 2020 21:38:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '487287c5-f5b8-4575-9afe-c44629c73cde' User entered 'No (N)'	System	30 Sep 2020 21:38:27
	System	30 Sep 2020 21:38:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '487287c5-f5b8-4575-9afe-c44629c73cde'	System	30 Sep 2020 21:38:27
User entered 'None (1)'	System	30 Sep 2020 21:38:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '487287c5-f5b8-4575-9afe-c44629c73cde' User entered '30 Sep 2020 17:38'	System	30 Sep 2020 21:38:27
	System	30 Sep 2020 21:38:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 3'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:07:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3'	System	01 Oct 2020 22:08:40
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:07:19', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3'	System	01 Oct 2020 22:08:40
User entered 'No (N)'	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:07:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3' User entered 'Yes (Y)'	System	01 Oct 2020 22:08:40
	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:07:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3' User entered '100'	System	01 Oct 2020 22:08:40
	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:08:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3'	System	01 Oct 2020 22:08:40
User entered 'None (1)'	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:08:35', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e9aef53a-0666-4396-b7d7-9a967c58fed3' User entered '01 Oct 2020 18:08'	System	01 Oct 2020 22:08:40
	System	01 Oct 2020 22:08:40

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 4'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:06:59', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1db88498-2524-4fc4-847e-b104cd799eab'	System	02 Oct 2020 21:07:56
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 21:07:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:07:13', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1db88498-2524-4fc4-847e-b104cd799eab' User entered 'No (N)'	System	02 Oct 2020 21:07:56
	System	02 Oct 2020 21:07:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:07:23', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1db88498-2524-4fc4-847e-b104cd799eab' User entered 'No (N)'	System	02 Oct 2020 21:07:56
	System	02 Oct 2020 21:07:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:07:34', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1db88498-2524-4fc4-847e-b104cd799eab' User entered 'None (1)'	System	02 Oct 2020 21:07:56
	System	02 Oct 2020 21:07:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:07:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1db88498-2524-4fc4-847e-b104cd799eab' User entered '02 Oct 2020 17:07'	System	02 Oct 2020 21:07:56
	System	02 Oct 2020 21:07:56

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 5'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:49:37', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e6d3a416-e0e2-4781-8854-c48c8121b474'	System	03 Oct 2020 21:50:27
User entered 'None (1)'	System	03 Oct 2020 21:50:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:49:57', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e6d3a416-e0e2-4781-8854-c48c8121b474'	System	03 Oct 2020 21:50:27
User entered 'No (N)'	System	03 Oct 2020 21:50:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:08', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e6d3a416-e0e2-4781-8854-c48c8121b474'	System	03 Oct 2020 21:50:27
User entered 'No (N)'	System	03 Oct 2020 21:50:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e6d3a416-e0e2-4781-8854-c48c8121b474'	System	03 Oct 2020 21:50:27
User entered 'None (1)'	System	03 Oct 2020 21:50:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'e6d3a416-e0e2-4781-8854-c48c8121b474' User entered '03 Oct 2020 17:50'	System	03 Oct 2020 21:50:27
	System	03 Oct 2020 21:50:27

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 6'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:55:08', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a9dfe8a5-c33b-4484-9935-30dbac1144ec'	System	05 Oct 2020 00:56:05
User entered 'None (1)'	System	05 Oct 2020 00:56:05

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:55:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a9dfe8a5-c33b-4484-9935-30dbac1144ec' User entered 'No (N)'	System	05 Oct 2020 00:56:05
	System	05 Oct 2020 00:56:05

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:55:31', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a9dfe8a5-c33b-4484-9935-30dbac1144ec' User entered 'No (N)'	System	05 Oct 2020 00:56:05
	System	05 Oct 2020 00:56:05

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:55:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a9dfe8a5-c33b-4484-9935-30dbac1144ec'	System	05 Oct 2020 00:56:05
User entered 'None (1)'	System	05 Oct 2020 00:56:05

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:56:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a9dfe8a5-c33b-4484-9935-30dbac1144ec' User entered '04 Oct 2020 20:56'	System	05 Oct 2020 00:56:05
	System	05 Oct 2020 00:56:05

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 7'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:22:42', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bac1a4f1-b2a1-418e-9dc9-a4d937f20d29'	System	05 Oct 2020 21:23:20
User entered 'None (1)'	System	05 Oct 2020 21:23:20

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:22:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bac1a4f1-b2a1-418e-9dc9-a4d937f20d29' User entered 'No (N)'	System	05 Oct 2020 21:23:20
	System	05 Oct 2020 21:23:20

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:00', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bac1a4f1-b2a1-418e-9dc9-a4d937f20d29' User entered 'No (N)'	System	05 Oct 2020 21:23:20
	System	05 Oct 2020 21:23:20

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bac1a4f1-b2a1-418e-9dc9-a4d937f20d29'	System	05 Oct 2020 21:23:20
User entered 'None (1)'	System	05 Oct 2020 21:23:20

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bac1a4f1-b2a1-418e-9dc9-a4d937f20d29' User entered '05 Oct 2020 17:23'	System	05 Oct 2020 21:23:20
	System	05 Oct 2020 21:23:20

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:30', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:43', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:47', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'None (0)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:31:59', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered 'No (N)'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-29T15:32:06', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1ecac2d8-e941-43b8-802e-609f4213003d' User entered '29 Sep 2020 15:32'	System	29 Sep 2020 19:32:11
	System	29 Sep 2020 19:32:11

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 15:26'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 17:56'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Sep 2020 18:51'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 2'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:38:57', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:39:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'None (0)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:39:10', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered 'No (N)'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-09-30T17:39:16', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '50ee061c-a401-43fe-a453-c0bb2eba5966' User entered '30 Sep 2020 17:39'	System	30 Sep 2020 21:39:19
	System	30 Sep 2020 21:39:19

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 3'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:03', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb'	System	01 Oct 2020 22:10:12
User entered 'None (0)'	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:15', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb' User entered 'None (0)'	System	01 Oct 2020 22:10:12
	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:23', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb'	System	01 Oct 2020 22:10:12
User entered 'None (0)'	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb' User entered 'None (0)'	System	01 Oct 2020 22:10:12
	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb'	System	01 Oct 2020 22:10:12
User entered 'None (0)'	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb' User entered 'None (0)'	System	01 Oct 2020 22:10:12
	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:09:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb'	System	01 Oct 2020 22:10:12
User entered 'No (N)'	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-01T18:10:10', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '8357453e-717e-42ee-bfbf-f868cadf89fb' User entered '01 Oct 2020 18:10'	System	01 Oct 2020 22:10:12
	System	01 Oct 2020 22:10:12

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 4'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:05', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'None (0)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'None (0)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'None (0)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:26', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'None (0)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0'	System	02 Oct 2020 21:09:08
User entered 'None (0)'	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'None (0)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:08:55', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered 'No (N)'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-02T17:09:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '73eb0345-f4ee-48aa-832c-ca39e6e995e0' User entered '02 Oct 2020 17:09'	System	02 Oct 2020 21:09:08
	System	02 Oct 2020 21:09:08

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 5'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:35', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:42', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:50:55', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:51:03', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:51:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:51:15', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'None (0)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:51:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered 'No (N)'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-03T17:51:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4117d455-e516-4679-b801-1f9b66e82bae' User entered '03 Oct 2020 17:51'	System	03 Oct 2020 21:51:36
	System	03 Oct 2020 21:51:36

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 6'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:56:12', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:22', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:36', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'None (0)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered 'No (N)'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-04T20:57:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7611aaf0-fbd1-4bfd-a901-279094df1f98'	System	05 Oct 2020 00:57:55
User entered '04 Oct 2020 20:57'	System	05 Oct 2020 00:57:55

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	29 Sep 2020 19:09:38
User entered 'Day 7'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:45', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:23:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:24:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:24:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:24:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'None (0)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:24:43', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered 'No (N)'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-05T17:24:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '58cfa1a4-f36e-4383-a029-0f50915a8b9c' User entered '05 Oct 2020 17:24'	System	05 Oct 2020 21:24:53
	System	05 Oct 2020 21:24:53

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:09:38

US3302465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:09:38

US3302465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	06 Oct 2020 19:05:30

US3302465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '6 Oct 2020'	(b) (4) Wendy Taylor (b) (4)	06 Oct 2020 19:05:30

US3302465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	06 Oct 2020 19:05:30

US3302465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) Wendy Taylor (b) (4)	06 Oct 2020 19:05:30

US3302465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 19:05:37

US3302465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '1'	System	06 Oct 2020 19:05:37

US3302465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:06:05

US3302465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:06:05

US3302465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:06:05

US3302465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:06:05

US3302465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:06:08

US3302465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '1'	System	14 Oct 2020 12:06:08

US3302465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:25:48

US3302465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:25:48

US3302465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:25:48

US3302465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:25:48

US3302465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:25:52

US3302465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:45
User entered '1'	System	20 Oct 2020 15:25:52

US3302465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 14:48:10

US3302465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 14:48:10

US3302465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[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 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	27 Oct 2020 14:48:10

US3302465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'VISIT2'	System	27 Oct 2020 14:48:10

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '09:58'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '27 Oct 2020 09:58'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '97.7' F	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '86'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'bpm'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '16'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'breaths/min'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '146'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '84'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '11:10'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '27 Oct 2020 11:10'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '97.7' F	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '82'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'bpm'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '18'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'breaths/min'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '138'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '91'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	27 Oct 2020 15:24:22

US3302465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:30

US3302465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:30

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '10:40'	Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '27 Oct 2020 10:40'	System	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'ONCE'	System	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 14:48:25

US3302465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:38

US3302465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:38

US3302465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '10:08'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:38

US3302465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '27 Oct 2020 10:08'	System	27 Oct 2020 15:24:38

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '27 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered '10:05'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '27 Oct 2020 10:05'	System	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '10:05'	(b) (4) Brittany Belcher (b) (4)	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '27 Oct 2020 10:05'	System	27 Oct 2020 15:24:50

US3302465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	27 Oct 2020 15:24:54

US3302465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '1'	System	27 Oct 2020 15:24:54

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:08:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bc87802b-3816-4dd6-a64f-bfa7c1221a9d' User entered 'Yes (Y)'	System	27 Oct 2020 15:09:00
	System	27 Oct 2020 15:09:00

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:08:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bc87802b-3816-4dd6-a64f-bfa7c1221a9d' User entered '97.7'	System	27 Oct 2020 15:09:00
	System	27 Oct 2020 15:09:00

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:08:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bc87802b-3816-4dd6-a64f-bfa7c1221a9d'	System	27 Oct 2020 15:09:00
User entered 'No (N)'	System	27 Oct 2020 15:09:00

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:08:58', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'bc87802b-3816-4dd6-a64f-bfa7c1221a9d' User entered '27 Oct 2020 11:08'	System	27 Oct 2020 15:09:00
	System	27 Oct 2020 15:09:00

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 11:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 13:30'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:13:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2c0272cf-e00f-4645-a23a-a79e7302960a' User entered 'Yes (Y)'	System	28 Oct 2020 05:14:15
	System	28 Oct 2020 05:14:15

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:13:49', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2c0272cf-e00f-4645-a23a-a79e7302960a' User entered '98.3'	System	28 Oct 2020 05:14:15
	System	28 Oct 2020 05:14:15

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:13:57', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2c0272cf-e00f-4645-a23a-a79e7302960a' User entered 'No (N)'	System	28 Oct 2020 05:14:15
	System	28 Oct 2020 05:14:15

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:12', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2c0272cf-e00f-4645-a23a-a79e7302960a' User entered '28 Oct 2020 01:14'	System	28 Oct 2020 05:14:15
	System	28 Oct 2020 05:14:15

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 14:25'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 2'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:03:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b' User entered 'Yes (Y)'	System	28 Oct 2020 16:04:53
	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:03:40', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b' User entered '98.6'	System	28 Oct 2020 16:04:53
	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:03:58', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b' User entered 'Yes (Y)'	System	28 Oct 2020 16:04:53
	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 15:13:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Brittany Belcher (b) (4)	28 Oct 2020 18:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:04:29', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b'	System	28 Oct 2020 16:04:53
User entered '1'	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:04:29', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b' User entered '0'	System	28 Oct 2020 16:04:53
	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:04:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '216fd815-8d4a-4b76-b56c-0798efc7f61b' User entered '28 Oct 2020 12:04'	System	28 Oct 2020 16:04:53
	System	28 Oct 2020 16:04:53

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 3'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:02:28', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'b7c85e12-9c31-45a4-9d82-2725c402766c' User entered 'Yes (Y)'	System	30 Oct 2020 23:47:07
	System	30 Oct 2020 23:47:07

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:02:42', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'b7c85e12-9c31-45a4-9d82-2725c402766c' User entered '98.5'	System	30 Oct 2020 23:47:07
	System	30 Oct 2020 23:47:07

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:02:51', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'b7c85e12-9c31-45a4-9d82-2725c402766c' User entered 'No (N)'	System	30 Oct 2020 23:47:07
	System	30 Oct 2020 23:47:07

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:03:03', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'b7c85e12-9c31-45a4-9d82-2725c402766c' User entered '29 Oct 2020 12:03'	System	30 Oct 2020 23:47:07
	System	30 Oct 2020 23:47:07

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 4'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:47:28', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c75ca005-2f0c-43b2-8f5d-3786344309cf' User entered 'Yes (Y)'	System	30 Oct 2020 23:48:09
	System	30 Oct 2020 23:48:09

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:47:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c75ca005-2f0c-43b2-8f5d-3786344309cf' User entered '98.6'	System	30 Oct 2020 23:48:09
	System	30 Oct 2020 23:48:09

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:47:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c75ca005-2f0c-43b2-8f5d-3786344309cf' User entered 'No (N)'	System	30 Oct 2020 23:48:09
	System	30 Oct 2020 23:48:09

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:48:05', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c75ca005-2f0c-43b2-8f5d-3786344309cf' User entered '30 Oct 2020 19:48'	System	30 Oct 2020 23:48:09
	System	30 Oct 2020 23:48:09

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 5'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:22:41', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '85e96487-d194-413b-8d85-a9652badc3ef' User entered 'Yes (Y)'	System	31 Oct 2020 18:23:46
	System	31 Oct 2020 18:23:46

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:23:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '85e96487-d194-413b-8d85-a9652badc3ef' User entered '98.5'	System	31 Oct 2020 18:23:46
	System	31 Oct 2020 18:23:46

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:23:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '85e96487-d194-413b-8d85-a9652badc3ef' User entered 'No (N)'	System	31 Oct 2020 18:23:46
	System	31 Oct 2020 18:23:46

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:23:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '85e96487-d194-413b-8d85-a9652badc3ef' User entered '31 Oct 2020 14:23'	System	31 Oct 2020 18:23:46
	System	31 Oct 2020 18:23:46

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 6'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T16:48:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f33cfc46-d97a-4396-ac21-c1de5e33f850'	System	01 Nov 2020 22:10:14
User entered 'Yes (Y)'	System	01 Nov 2020 22:10:14

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:09:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f33cfc46-d97a-4396-ac21-c1de5e33f850' User entered '98.6'	System	01 Nov 2020 22:10:14
	System	01 Nov 2020 22:10:14

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:09:58', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f33cfc46-d97a-4396-ac21-c1de5e33f850'	System	01 Nov 2020 22:10:14
User entered 'No (N)'	System	01 Nov 2020 22:10:14

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:10:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f33cfc46-d97a-4396-ac21-c1de5e33f850'	System	01 Nov 2020 22:10:14
User entered '01 Nov 2020 17:10'	System	01 Nov 2020 22:10:14

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 7'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:07:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c60a79c2-033c-43ad-97a7-47b5e84b5501'	System	02 Nov 2020 17:08:25
User entered 'Yes (Y)'	System	02 Nov 2020 17:08:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:07:59', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c60a79c2-033c-43ad-97a7-47b5e84b5501'	System	02 Nov 2020 17:08:25
User entered '98.5'	System	02 Nov 2020 17:08:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:06', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c60a79c2-033c-43ad-97a7-47b5e84b5501'	System	02 Nov 2020 17:08:25
User entered 'No (N)'	System	02 Nov 2020 17:08:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:15', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'c60a79c2-033c-43ad-97a7-47b5e84b5501'	System	02 Nov 2020 17:08:25
User entered '02 Nov 2020 12:08'	System	02 Nov 2020 17:08:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:04', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d17d88b-6243-40da-afce-5e69116b9183'	System	27 Oct 2020 15:09:24
User entered 'None (1)'	System	27 Oct 2020 15:09:24

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:08', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d17d88b-6243-40da-afce-5e69116b9183'	System	27 Oct 2020 15:09:24
User entered 'No (N)'	System	27 Oct 2020 15:09:24

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d17d88b-6243-40da-afce-5e69116b9183'	System	27 Oct 2020 15:09:24
User entered 'No (N)'	System	27 Oct 2020 15:09:24

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:19', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d17d88b-6243-40da-afce-5e69116b9183'	System	27 Oct 2020 15:09:24
User entered 'None (1)'	System	27 Oct 2020 15:09:24

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:22', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d17d88b-6243-40da-afce-5e69116b9183' User entered '27 Oct 2020 11:09'	System	27 Oct 2020 15:09:24
	System	27 Oct 2020 15:09:24

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 11:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 13:30'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '70876d5a-5a3f-44ad-a5db-641918005b03'	System	28 Oct 2020 05:14:57
User entered 'None (1)'	System	28 Oct 2020 05:14:57

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:30', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '70876d5a-5a3f-44ad-a5db-641918005b03'	System	28 Oct 2020 05:14:57
User entered 'No (N)'	System	28 Oct 2020 05:14:57

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '70876d5a-5a3f-44ad-a5db-641918005b03'	System	28 Oct 2020 05:14:57
User entered 'No (N)'	System	28 Oct 2020 05:14:57

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:45', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '70876d5a-5a3f-44ad-a5db-641918005b03'	System	28 Oct 2020 05:14:57
User entered 'None (1)'	System	28 Oct 2020 05:14:57

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:14:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '70876d5a-5a3f-44ad-a5db-641918005b03' User entered '28 Oct 2020 01:14'	System	28 Oct 2020 05:14:57
	System	28 Oct 2020 05:14:57

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 14:25'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 2'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:05:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:06:14', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered 'No (N)'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:07:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered 'Yes (Y)'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:14:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered '6'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:14:31', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered 'None (1)'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:14:51', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f31d8161-caa2-4835-9f09-4668d6fe7a75'	System	28 Oct 2020 16:14:54
User entered '28 Oct 2020 12:14'	System	28 Oct 2020 16:14:54

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 3'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:05:22', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:05:35', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered 'Yes (Y)'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:05:50', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered '5'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:06:10', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered 'Yes (Y)'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:06:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered '6'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:06:30', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f'	System	30 Oct 2020 23:47:08
User entered 'None (1)'	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '995de14a-d967-4ac7-a98d-a8fe5b45935f' User entered '29 Oct 2020 12:07'	System	30 Oct 2020 23:47:08
	System	30 Oct 2020 23:47:08

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 4'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:49:22', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f5a16ca7-9f3c-4cc0-9e7f-46e8b645ae72'	System	30 Oct 2020 23:50:23
User entered 'None (1)'	System	30 Oct 2020 23:50:23

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:49:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f5a16ca7-9f3c-4cc0-9e7f-46e8b645ae72'	System	30 Oct 2020 23:50:23
User entered 'No (N)'	System	30 Oct 2020 23:50:23

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:49:34', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f5a16ca7-9f3c-4cc0-9e7f-46e8b645ae72'	System	30 Oct 2020 23:50:23
User entered 'No (N)'	System	30 Oct 2020 23:50:23

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:49:45', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f5a16ca7-9f3c-4cc0-9e7f-46e8b645ae72'	System	30 Oct 2020 23:50:23
User entered 'None (1)'	System	30 Oct 2020 23:50:23

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:50:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'f5a16ca7-9f3c-4cc0-9e7f-46e8b645ae72' User entered '30 Oct 2020 19:50'	System	30 Oct 2020 23:50:23
	System	30 Oct 2020 23:50:23

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 5'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5574f4d6-2323-4fec-b767-6572bb8b1d27'	System	31 Oct 2020 18:24:36
User entered 'None (1)'	System	31 Oct 2020 18:24:36

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5574f4d6-2323-4fec-b767-6572bb8b1d27'	System	31 Oct 2020 18:24:36
User entered 'No (N)'	System	31 Oct 2020 18:24:36

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5574f4d6-2323-4fec-b767-6572bb8b1d27' User entered 'No (N)'	System	31 Oct 2020 18:24:36
	System	31 Oct 2020 18:24:36

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5574f4d6-2323-4fec-b767-6572bb8b1d27'	System	31 Oct 2020 18:24:36
User entered 'None (1)'	System	31 Oct 2020 18:24:36

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5574f4d6-2323-4fec-b767-6572bb8b1d27' User entered '31 Oct 2020 14:24'	System	31 Oct 2020 18:24:36
	System	31 Oct 2020 18:24:36

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 6'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:10:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c8f6521-d62a-4a5e-8aae-d1c00aac609'	System	01 Nov 2020 22:12:06
User entered 'None (1)'	System	01 Nov 2020 22:12:06

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:10:58', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c8f6521-d62a-4a5e-8aae-d1c00aac609'	System	01 Nov 2020 22:12:06
User entered 'No (N)'	System	01 Nov 2020 22:12:06

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:11:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c8f6521-d62a-4a5e-8aae-d1c00aac609'	System	01 Nov 2020 22:12:06
User entered 'No (N)'	System	01 Nov 2020 22:12:06

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:11:56', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c8f6521-d62a-4a5e-8aae-d1c00aac609'	System	01 Nov 2020 22:12:06
User entered 'None (1)'	System	01 Nov 2020 22:12:06

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:03', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c8f6521-d62a-4a5e-8aae-d1c00aac609' User entered '01 Nov 2020 17:12'	System	01 Nov 2020 22:12:06
	System	01 Nov 2020 22:12:06

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 7'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a8ab0693-b062-4a1c-8fab-c059e5595dcd' User entered 'None (1)'	System	02 Nov 2020 17:09:04
	System	02 Nov 2020 17:09:04

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:39', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a8ab0693-b062-4a1c-8fab-c059e5595dcd' User entered 'No (N)'	System	02 Nov 2020 17:09:04
	System	02 Nov 2020 17:09:04

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a8ab0693-b062-4a1c-8fab-c059e5595dcd' User entered 'No (N)'	System	02 Nov 2020 17:09:04
	System	02 Nov 2020 17:09:04

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:08:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a8ab0693-b062-4a1c-8fab-c059e5595dcd' User entered 'None (1)'	System	02 Nov 2020 17:09:04
	System	02 Nov 2020 17:09:04

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a8ab0693-b062-4a1c-8fab-c059e5595dcd' User entered '02 Nov 2020 12:09'	System	02 Nov 2020 17:09:04
	System	02 Nov 2020 17:09:04

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:30', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'None (0)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'None (0)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:37', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d'	System	27 Oct 2020 15:09:54
User entered 'None (0)'	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:41', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'None (0)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'None (0)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:46', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'None (0)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:50', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered 'No (N)'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-27T11:09:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7c807525-8540-406a-96e4-c3d23e20297d' User entered '27 Oct 2020 11:09'	System	27 Oct 2020 15:09:54
	System	27 Oct 2020 15:09:54

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 11:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 13:30'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:13', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:21', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:25', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'None (0)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:35', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered 'No (N)'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T01:15:41', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7728e086-d4fb-4003-9ab4-061b564d8c76' User entered '28 Oct 2020 01:15'	System	28 Oct 2020 05:15:45
	System	28 Oct 2020 05:15:45

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '27 Oct 2020 14:25'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 2'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'None (0)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:09', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'None (0)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'No interference with activity (1)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'None (0)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'None (0)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:15:56', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'None (0)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:16:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered 'No (N)'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-28T12:16:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd491ef91-32ef-4ea5-9d8b-97d10a49e001' User entered '28 Oct 2020 12:16'	System	28 Oct 2020 16:16:38
	System	28 Oct 2020 16:16:38

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 3'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:40', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:47', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:49', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:07:53', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'None (0)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:08:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered 'No (N)'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-29T12:08:07', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '2ac54d7c-004b-4038-ae89-8b47b26a6ded' User entered '29 Oct 2020 12:08'	System	30 Oct 2020 23:47:09
	System	30 Oct 2020 23:47:09

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 4'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:50:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:50:37', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:50:52', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:50:57', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:51:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:51:05', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'None (0)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:51:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered 'No (N)'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-30T19:51:21', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7abb8a23-2815-4906-bef9-435daea004b8' User entered '30 Oct 2020 19:51'	System	30 Oct 2020 23:51:41
	System	30 Oct 2020 23:51:41

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 5'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:50', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:24:54', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:02', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:06', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:11', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:15', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'None (0)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered 'No (N)'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-10-31T14:25:30', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'eff28b68-e682-4c17-a10c-c01e88832d40' User entered '31 Oct 2020 14:25'	System	31 Oct 2020 18:25:35
	System	31 Oct 2020 18:25:35

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 6'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:14', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702'	System	01 Nov 2020 22:13:04
User entered 'None (0)'	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:23', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered 'None (0)'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:28', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered 'None (0)'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered 'None (0)'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered 'None (0)'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:47', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered 'None (0)'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:12:56', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702'	System	01 Nov 2020 22:13:04
User entered 'No (N)'	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-01T17:13:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd614908e-f219-49bd-820b-87e4106c7702' User entered '01 Nov 2020 17:13'	System	01 Nov 2020 22:13:04
	System	01 Nov 2020 22:13:04

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
Data entry locked.	System	27 Oct 2020 14:48:25
User entered 'Day 7'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:13', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:24', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:42', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'None (0)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

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 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:50', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered 'No (N)'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-02T12:09:57', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '98e9b076-f5d9-4ebc-997c-d04c4323007e' User entered '02 Nov 2020 12:09'	System	02 Nov 2020 17:10:00
	System	02 Nov 2020 17:10:00

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 14:48:25

US3302465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:58:38
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 14:48:25

US3302465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:13:28

US3302465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:13:28

US3302465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:13:28

US3302465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:13:28

US3302465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:13:31

US3302465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '1'	System	03 Nov 2020 16:13:31

US3302465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:44:34

US3302465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:44:34

US3302465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:44:34

US3302465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:44:34

US3302465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:44:27

US3302465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '1'	System	12 Nov 2020 15:44:27

US3302465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:54:12

US3302465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:54:12

US3302465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:54:12

US3302465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:54:12

US3302465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:54:19

US3302465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '1'	System	17 Nov 2020 15:54:19

US3302465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:13

US3302465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:13

US3302465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[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 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:13

US3302465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'VISIT3'	System	23 Nov 2020 18:19:13

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '10:37'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '23 Nov 2020 10:37'	System	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '82'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'bpm'	System	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '18'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'breaths/min'	System	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '149'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '88'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered 'mmHg'	System	23 Nov 2020 18:19:42

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23

US3302465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23

US3302465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:58

US3302465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:58

US3302465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:54

US3302465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:54

US3302465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '10:40'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:54

US3302465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '23 Nov 2020 10:40'	System	23 Nov 2020 18:19:54

US3302465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:20:01

US3302465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:23
User entered '1'	System	23 Nov 2020 18:20:01

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-30T14:07:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a10b2541-d9c9-4588-a8df-c3b7579617f2'	System	30 Nov 2020 19:08:44
User entered 'No (N)'	System	30 Nov 2020 19:08:44

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-30T14:07:21', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a10b2541-d9c9-4588-a8df-c3b7579617f2'	System	30 Nov 2020 19:08:44
User entered 'No (N)'	System	30 Nov 2020 19:08:44

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-11-30T14:08:01', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'a10b2541-d9c9-4588-a8df-c3b7579617f2' User entered '30 Nov 2020 14:08:01'	System	30 Nov 2020 19:08:44
	System	30 Nov 2020 19:08:44

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-03T10:53:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c08b072-12c1-49ef-877c-ebded9cbb562'	System	03 Dec 2020 15:54:07
User entered 'No (N)'	System	03 Dec 2020 15:54:07

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-03T10:53:48', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c08b072-12c1-49ef-877c-ebded9cbb562'	System	03 Dec 2020 15:54:07
User entered 'No (N)'	System	03 Dec 2020 15:54:07

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-03T10:54:04', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '5c08b072-12c1-49ef-877c-ebded9cbb562' User entered '03 Dec 2020 10:54:04'	System	03 Dec 2020 15:54:07
	System	03 Dec 2020 15:54:07

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-11T12:39:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d8ece39-2768-446e-b5cc-50e058cbc370'	System	11 Dec 2020 17:39:57
User entered 'No (N)'	System	11 Dec 2020 17:39:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-11T12:39:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d8ece39-2768-446e-b5cc-50e058cbc370'	System	11 Dec 2020 17:39:57
User entered 'No (N)'	System	11 Dec 2020 17:39:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-11T12:39:55', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '3d8ece39-2768-446e-b5cc-50e058cbc370' User entered '11 Dec 2020 12:39:55'	System	11 Dec 2020 17:39:57
	System	11 Dec 2020 17:39:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-17T10:41:38', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4a824b4c-2cc7-4105-9901-ab59cb808396'	System	17 Dec 2020 15:42:10
User entered 'No (N)'	System	17 Dec 2020 15:42:10

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-17T10:41:45', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4a824b4c-2cc7-4105-9901-ab59cb808396'	System	17 Dec 2020 15:42:10
User entered 'No (N)'	System	17 Dec 2020 15:42:10

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-17T10:41:55', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '4a824b4c-2cc7-4105-9901-ab59cb808396' User entered '17 Dec 2020 10:41:55'	System	17 Dec 2020 15:42:10
	System	17 Dec 2020 15:42:10

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-24T12:03:27', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '27399d46-e003-4ade-9510-2542878e5fd7'	System	24 Dec 2020 17:04:23
User entered 'No (N)'	System	24 Dec 2020 17:04:23

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-24T12:03:44', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '27399d46-e003-4ade-9510-2542878e5fd7'	System	24 Dec 2020 17:04:23
User entered 'No (N)'	System	24 Dec 2020 17:04:23

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-24T12:04:20', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '27399d46-e003-4ade-9510-2542878e5fd7' User entered '24 Dec 2020 12:04:20'	System	24 Dec 2020 17:04:23
	System	24 Dec 2020 17:04:23

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-31T12:48:17', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '66f30947-ed1e-40fd-91f8-165ff27863fd' User entered 'No (N)'	System	31 Dec 2020 17:48:57
	System	31 Dec 2020 17:48:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-31T12:48:33', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '66f30947-ed1e-40fd-91f8-165ff27863fd'	System	31 Dec 2020 17:48:57
User entered 'No (N)'	System	31 Dec 2020 17:48:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2020-12-31T12:48:55', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '66f30947-ed1e-40fd-91f8-165ff27863fd' User entered '31 Dec 2020 12:48:55'	System	31 Dec 2020 17:48:57
	System	31 Dec 2020 17:48:57

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-07T08:12:14', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1c54ca32-c722-4537-b5d1-2f8b2dbbcfd6'	System	07 Jan 2021 13:12:56
User entered 'No (N)'	System	07 Jan 2021 13:12:56

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-07T08:12:31', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1c54ca32-c722-4537-b5d1-2f8b2dbbcfd6'	System	07 Jan 2021 13:12:56
User entered 'No (N)'	System	07 Jan 2021 13:12:56

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-07T08:12:51', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '1c54ca32-c722-4537-b5d1-2f8b2dbbcfd6' User entered '07 Jan 2021 08:12:51'	System	07 Jan 2021 13:12:56
	System	07 Jan 2021 13:12:56

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-14T12:57:40', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7439a12a-7f44-42e1-9bc5-f48640dc441d'	System	14 Jan 2021 17:58:09
User entered 'No (N)'	System	14 Jan 2021 17:58:09

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-14T12:57:56', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7439a12a-7f44-42e1-9bc5-f48640dc441d'	System	14 Jan 2021 17:58:09
User entered 'No (N)'	System	14 Jan 2021 17:58:09

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-14T12:58:05', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: '7439a12a-7f44-42e1-9bc5-f48640dc441d' User entered '14 Jan 2021 12:58:05'	System	14 Jan 2021 17:58:09
	System	14 Jan 2021 17:58:09

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Have you experienced any new COVID-19 disease symptoms 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)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Have you had to contact a healthcare provider 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)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-29T14:12:00', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd5704970-c3b6-4aa6-bbef-b76739209f9e'	System	29 Jan 2021 19:12:47
User entered 'No (N)'	System	29 Jan 2021 19:12:47

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-29T14:12:32', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd5704970-c3b6-4aa6-bbef-b76739209f9e'	System	29 Jan 2021 19:12:47
User entered 'No (N)'	System	29 Jan 2021 19:12:47

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF68FB4-9791-4A86-A91F-B9630D36BDE4)', Time: '2021-01-29T14:12:43', User OID: 'PatientReportedOutcome (US3302465)', ODM File OID: 'd5704970-c3b6-4aa6-bbef-b76739209f9e' User entered '29 Jan 2021 14:12:43'	System	29 Jan 2021 19:12:47
	System	29 Jan 2021 19:12:47

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 11:13:15

US3302465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:13:15
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 11:13:15

US3302465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Dec 2020 15:16:50

US3302465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '22 Dec 2020'	(b) (4) Brittany Belcher (b) (4)	22 Dec 2020 15:16:50

US3302465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Contact Made (CONTACT MADE)'	Brittany Belcher (b) (4)	22 Dec 2020 15:16:50

US3302465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered empty.	Brittany Belcher (b) (4)	22 Dec 2020 15:16:50

US3302465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Dec 2020 15:16:54

US3302465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:42:19
User entered '1'	System	22 Dec 2020 15:16:54

US3302465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:54:56

US3302465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:54:56

US3302465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:54:56

US3302465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:54:56

US3302465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:55:04

US3302465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered empty.	System	02 Apr 2021 14:55:04

US3302465

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

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:10

US3302465

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

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:10

US3302465

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

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:10

US3302465

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

Form: Visit Date

Generated On: 09 Jun 2021 17:03:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 19:58:10

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:55
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 17:58:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:19:25

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:55
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:40:50
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	12 Apr 2021 17:58:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brittany Belcher (b) (4)	12 Apr 2021 17:58:02
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:20:47
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:19:25

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 09:47:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 09:47:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered empty.	System	12 Jan 2021 19:58:04

US3302465

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

Form: Unblinding

Generated On: 09 Jun 2021 17:03:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered empty.	System	12 Jan 2021 19:58:04

US3302465

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:55

US3302465

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:55

US3302465

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '13:02'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:55

US3302465

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered '12 Jan 2021 13:02'	System	12 Jan 2021 19:57:55

US3302465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:43

US3302465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:43

US3302465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '13:00'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:57:43

US3302465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:12
User entered '12 Jan 2021 13:00'	System	12 Jan 2021 19:57:43

US3302465

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:46
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	21 Jan 2021 18:17:03

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:27:00
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:11:40
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:11:31
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 18:11:31
User entered 'USA-US087-2021-mRNA-1273-P301000012' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 18:11:31
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:19:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:17:50
User entered 'USA-US087-2021-mRNA-1273-P301000016'	System	01 Feb 2021 19:17:40
User entered 'New'	(b) (4), (b) (6)	01 Feb 2021 19:17:40

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:14
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:10:21
Data point term sent to Coder	System	29 Jan 2021 18:10:19
User entered 'Myocardial Infarction'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:16
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:19
User entered 'No (N)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:20
User entered 'No (N)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:22
User entered '29 Jan 2021'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:24
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered empty.	System	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:25
User entered 'No (N)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:27
User entered '29 Jan 2021'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:29
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered empty.	System	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:04
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
User closed query 'Severity in EDC only goes up to Grade 4. The severity in the source should have the same range as EDC, so the source needs to be revised.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:47:06
Query 'Severity in EDC only goes up to Grade 4. The severity in the source should have the same range as EDC, so the source needs to be revised.' answered with 'CRIO changed to reflect grade 4' (Site from CRA).	Wendy Taylor (b) (4)	02 Mar 2021 21:36:46
User opened query 'Severity in EDC only goes up to Grade 4. The severity in the source should have the same range as EDC, so the source needs to be revised.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 04:43:45
User closed query 'Per source the severity is documented as Grade 5. Kindly review the source, and update accordingly ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 04:43:45
Query 'Per source the severity is documented as Grade 5. Kindly review the source, and update accordingly ' answered with 'Per Source Maximum Grade or Intensity is documented as Death or Grade 5. Subject is deceased. Please advise how to document for EDC to match source. ' (Site from CRA).	Brittany Belcher (b) (4)	19 Feb 2021 15:57:36
User opened query 'Per source the severity is documented as Grade 5. Kindly review the source, and update accordingly ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 17:30:46
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 17:29:15
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:19:33
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 18:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 18:10:16
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:10:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Severity](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 18:09:56
User entered empty.	Wendy Taylor (b) (4) [REDACTED] [REDACTED]	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:31
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:48
User entered '1'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:46
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:44
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:42
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:38
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:37
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:35
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:31
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:30
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:28
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:26
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:25
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

US3302465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:23
User entered 'Not Applicable (NOT APPLICABLE)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
Signature has been broken.	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 14:34:19
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:22
User entered '1'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:06
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:04
User entered '0'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:20:02
User entered 'Fatal (FATAL)'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:19:55
User entered empty.	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:30
User closed query 'Please update narrative with Progress Note information dated 19Mar2021 in CRIO.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 20:55:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
Query 'Please update narrative with Progress Note information dated 19Mar2021 in CRIO.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	01 Apr 2021 14:48:27
Signature has been broken.	Brittany Belcher (b) (4)	01 Apr 2021 14:48:12
User entered '3/19/2021 Update: Site has reached out to family several times and have been unable to obtain any further information. subjects niece states they are not power of attorney and cannot sign a release to obtain medical records. per the vital records dept at srmc, only authorized family members can obtain a death certificate.' reason for change: Data Entry Error	Brittany Belcher (b) (4)	01 Apr 2021 14:48:12
User opened query 'Please update narrative with Progress Note information dated 19Mar2021 in CRIO.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:36:38
User closed query 'PV Query: Per recent query response, autopsy was not performed. However, EOS eCRF shows as Unknown. Please update EOS eCRF to reflect autopsy was not performed.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:20:53
Query 'PV Query: Per recent query response, autopsy was not performed. However, EOS eCRF shows as Unknown. Please update EOS eCRF to reflect autopsy was not performed.' answered with 'site has been unable to obtain any records on this subject, we do not have a medical records release, the family is not cooperating with the site as they state they do not have POA to be able to get records' (Site from Safety).	marsha gossett (b) (4)	19 Mar 2021 12:52:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per recent query response, autopsy was not performed. However, EOS eCRF shows as Unknown. Please update EOS eCRF to reflect autopsy was not performed.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 18:50:51
	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
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)	03 Mar 2021 15:42:35
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)	03 Mar 2021 15:42:27
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:42:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'subject did not sign a medical release of information' (Site from Safety).	Wendy Taylor (b) (4)	02 Mar 2021 21:38:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[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 'subject did not sign a medical release of information' (Site from Safety).	Wendy Taylor (b) (4)	02 Mar 2021 21:38:26
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 'autopsy not completed' (Site from Safety).	Wendy Taylor (b) (4)	02 Mar 2021 21:37:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:33:58
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:33:51
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)	05 Feb 2021 16:33:45
User entered 'Subjects niece called site and left message reporting that he had a myocardial infarction that led to death. Site returned call to get details of death and had to leave a message. Site reported SAE initial report will follow up once more detail are received.'	Wendy Taylor (b) (4)	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Jan 2021 18:09:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:03:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:31:05
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:02:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:04:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:04:53
Data point term sent to Coder	System	29 Sep 2020 20:04:05
User entered 'lisinopril'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'hypertension'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '10'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '804 (804)'	System	29 Sep 2020 20:03:18

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:04:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:04:52
Data point term sent to Coder	System	29 Sep 2020 20:04:06
User entered 'glipizide'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'diabetes mellitus type 2'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '5'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '2'	System	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '804 (804)'	System	29 Sep 2020 20:03:49

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: TAMULOSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:05:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:05:37
Data point term sent to Coder	System	29 Sep 2020 20:05:06
User entered 'tamulosin'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'bph'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:46:06
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 16:00:34
User entered '0.4' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 16:00:24
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:38:02
User entered '5'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'un UNK 2014'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '804 (804)'	System	29 Sep 2020 20:04:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: FESOTERODINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:07:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:07:41
Data point term sent to Coder	System	29 Sep 2020 20:05:06
User entered 'fesoterodine'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'polyuria'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:46:12
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'reported per patient' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 16:01:39
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:38:09
User entered '5'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '1'	System	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '804 (804)'	System	29 Sep 2020 20:04:40

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:55:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:55:10
Data point term sent to Coder	System	28 Oct 2020 18:56:26
User entered 'Tylenol'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 06:41:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' answered with 'this was taken during the 7 days post 1st vaccine' (Site from DM).	brittany cooksey (b) (4)	20 Jan 2021 19:21:42

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' (Site from DM). User entered 'injection pain'	(b) (4), (b) (6) [REDACTED]	20 Jan 2021 06:12:11
	Brittany Belcher (b) (4) [REDACTED] [REDACTED]	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '500'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '01 Oct 2020'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Please verify end date as Pain at injection Site is recorded with Grade 0 from 03 Oct 2020. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:46:56
Query 'Per DM CLR: Please verify end date as Pain at injection Site is recorded with Grade 0 from 03 Oct 2020. Update the eCRF as appropriate.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 20:12:08
User entered '01 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:10:53
User opened query 'Per DM CLR: Please verify end date as Pain at injection Site is recorded with Grade 0 from 03 Oct 2020. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:31:08
User entered '28 Oct 2020'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:46:19
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 20:12:12
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:10:53
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:31:26
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User entered empty.	System	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User entered empty.	System	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:05
User entered empty.	System	28 Oct 2020 18:56:12

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 20:32:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 20:32:48
Data point term sent to Coder	System	08 Dec 2020 20:13:46
User entered 'Tylenol'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 06:41:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' answered with 'This was taken during the post 7 days of 2nd injection' (Site from DM).	brittany cooksey (b) (4)	20 Jan 2021 19:22:20

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN did not meet the AE reporting criteria. ' (Site from DM). User entered 'injection pain'	(b) (4), (b) (6) [REDACTED]	20 Jan 2021 06:14:10
	brittany cooksey (b) (4) [REDACTED]	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '500'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'mg (mg)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'as needed (PRN)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered empty.	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '28 Oct 2020'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '0'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'No (N)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered '28 Oct 2020'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:36:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User entered empty.	System	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User entered empty.	System	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:08
User entered empty.	System	08 Dec 2020 20:13:07

US3302465

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:03:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	29 Sep 2020 20:04:45

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Jan 2021'	Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:57
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	08 Mar 2021 17:02:03
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	08 Mar 2021 17:02:03
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	05 Mar 2021 20:00:52
Signature has been broken.	Brittany Belcher (b) (4)	05 Mar 2021 20:00:52
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Mar 2021 20:00:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	19 Feb 2021 17:01:00
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	19 Feb 2021 17:01:00
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	19 Feb 2021 17:00:06
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	19 Feb 2021 17:00:06
User entered 'Death (DEATH)'	Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

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 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:57
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 (b) (4)	08 Mar 2021 17:02:15
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	08 Mar 2021 17:02:15
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	08 Mar 2021 17:02:03
Signature has been broken.	Brittany Belcher (b) (4)	05 Mar 2021 20:00:52
User entered 'Myocardial Infarction' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Mar 2021 20:00:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
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 (b) (4)	19 Feb 2021 17:01:17
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	19 Feb 2021 17:01:17
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 17:01:00

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). User entered 'Myocardial Infarction' reason for change: Data Entry Error	System Brittany Belcher (b) (4) [REDACTED]	19 Feb 2021 17:00:29 19 Feb 2021 17:00:29
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). User entered empty.	System Wendy Taylor (b) (4) [REDACTED]	19 Feb 2021 17:00:06 02 Feb 2021 15:48:35

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:57
Query 'Per CDM: Please consider updating "Adverse Event" to AE#2. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:41:31
User opened query 'Per CDM: Please consider updating "Adverse Event" to AE#2. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:41:03
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	16 Mar 2021 11:27:33
User closed query 'Per CDM re-query: Please consider entering here AE#2 instead of Other and specify. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:30:03
Query 'Per CDM re-query: Please consider entering here AE#2 instead of Other and specify. Thank you!' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	03 Mar 2021 20:09:05
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	03 Mar 2021 20:08:53
Signature has been broken.	Brittany Belcher (b) (4)	03 Mar 2021 20:08:53
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Mar 2021 20:08:53
User opened query 'Per CDM re-query: Please consider entering here AE#2 instead of Other and specify. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:17:23
User closed query 'Per CDM: Please consider updating "Adverse Event" to AE#2. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:17:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	19 Feb 2021 17:01:30
User entered 'Other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	19 Feb 2021 17:01:30

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Query 'Per CDM: Please consider updating "Adverse Event" to AE#2. Thank you!' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	19 Feb 2021 17:00:46
User opened query 'Per CDM: Please consider updating "Adverse Event" to AE#2. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:11:57
User closed query 'Per CDM: Please consider adding here AE or SAE with number (Example: AE#1) instead of "Other" and specify. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:13:42
Query 'Per CDM: Please consider adding here AE or SAE with number (Example: AE#1) instead of "Other" and specify. Thank you!' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	09 Feb 2021 15:06:06
User opened query 'Main cause of death is not Other, System however specify is provided. Please correct.' (Site from System).	System	09 Feb 2021 15:05:50
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	09 Feb 2021 15:05:50
User opened query 'Per CDM: Please consider adding here AE or SAE with number (Example: AE#1) instead of "Other" and specify. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:16:09
User closed query 'Main cause of death is not Other, System however specify is provided. Please correct.' (Site from System).	System	03 Feb 2021 15:26:45
User entered 'Other (OTHER)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Feb 2021 15:26:45
User opened query 'Main cause of death is not Other, System however specify is provided. Please correct.' (Site from System).	System	02 Feb 2021 15:48:35
User entered 'Unknown (UNKNOWN)'	Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:57
Signature has been broken.	(b) (4) Wendy Taylor (b) (4)	16 Mar 2021 11:27:33
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	16 Mar 2021 11:27:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Niece contacted site to let us know that subject had a Myocardial infarction and is deceased. Site will try to obtain more information.'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '29 Jan 2021'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

US3302465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:38

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered 'Unknown (UNK)'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 15:48:35

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'USA-US087-2021-MRNA-1273-P301000012'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Gregory'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Feldman'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '141 Harold Fleming Court'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Spartanburg'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered empty.	System	29 Jan 2021 18:11:10
User entered 'South Carolina'	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '29303'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'US'	System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '3'	System	02 Apr 2021 14:57:11
User entered '2'	System	03 Mar 2021 18:12:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'USA-US087-2021-MRNA-1273-P301000012'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Gregory'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Feldman'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '141 Harold Fleming Court'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Spartanburg'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered empty.	System	29 Jan 2021 18:11:10
User entered 'South Carolina'	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '29303'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'US'	System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '3'	System	02 Apr 2021 14:57:11
User entered '2'	System	03 Mar 2021 18:12:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered '22/Jan/2021 15:07'	System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'USA-US087-2021-MRNA-1273-P301000012'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Gregory'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Feldman'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '141 Harold Fleming Court'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Spartanburg'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered empty.	System	29 Jan 2021 18:11:10
User entered 'South Carolina'	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '29303'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'US'	System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '3'	System	02 Apr 2021 14:57:11
User entered '2'	System	03 Mar 2021 18:12:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:03:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
User entered '03/Mar/2021 13:12'	(b) (4) System	03 Mar 2021 18:12:20

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:21:30
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:20

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'USA-US087-2021-MRNA-1273-P301000012'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:28:52
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:12:08
DataPoint Un-verified.	System	03 Mar 2021 18:11:31
Signature has been broken.	System	03 Mar 2021 18:11:31
User entered 'Yes (Y)'	System	03 Mar 2021 18:11:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered 'No (N)'	System	29 Jan 2021 18:11:10
Un-reviewed for Safety.	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'No (N)'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Gregory'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Feldman'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '141 Harold Fleming Court'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'Spartanburg'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:12:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
User entered empty.	System	29 Jan 2021 18:11:10
User entered 'South Carolina'	Wendy Taylor (b) (4)	29 Jan 2021 18:11:10

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered '29303'	System	22 Jan 2021 20:06:29

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:14:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 20:07:26
User entered 'US'	System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User entered '3'	System	02 Apr 2021 14:57:11
User entered '2'	System	03 Mar 2021 18:12:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	22 Jan 2021 20:07:02

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:03:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered '02/Apr/2021 09:57'	(b) (4) System	02 Apr 2021 14:57:11

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:42
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:57:11

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'USA-US087-2021-MRNA-1273-P301000016'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Yes (Y)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Yes (Y)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Gregory'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Feldman'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered '141 Harold Fleming Court'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Spartanburg'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered '29303'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
User entered 'US'	System	01 Feb 2021 19:18:17

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	01 Feb 2021 19:18:17

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'USA-US087-2021-MRNA-1273-P301000016'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Yes (Y)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Yes (Y)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'No (N)'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Gregory'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Feldman'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered '141 Harold Fleming Court'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered 'Spartanburg'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 19:18:09
User entered '29303'	System	01 Feb 2021 19:17:40

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
User entered 'US'	System	01 Feb 2021 19:18:17

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
User entered '1'	(b) (4) System	01 Feb 2021 19:18:17

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:53:37
User entered '01/Feb/2021 19:18'	System	01 Feb 2021 19:18:17

US3302465

Folder: SAE USA-US087-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:38

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)	02 May 2021 14:02:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 17:53:37
User entered '1'	(b) (4), (b) (6)	01 Feb 2021 19:18:17