

US3302345 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

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US3302345

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

[Participant ID](#)

US3302345

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

US3302345

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Date of Birth (MMM yyyy)	(b) (6) 1994
Age	26
Age Units	YEARS
Age (Derived)	26
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Date of Informed Consent (*dd MMM yyyy*) 24 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:18:31

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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 19:18:31

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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 19:18:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 24 AUG 2020

Time of assessment (00:00-23:59) 11:50 (24 HR)

Vital Signs Date and Time (derived) 24 AUG 2020 11:50

Height (xxx.x) 66 in

Weight (xxx.x) 125 lb

BMI (xxx.x) 20.21771 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 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 24 AUG 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:18:31

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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 19:18:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 AUG 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 19:18:31

Generated On: 11 Aug 2021 22:13:06

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 107743

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 19:18:31

Generated On: 11 Aug 2021 22:13:06

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 19:18:31

Generated On: 11 Aug 2021 22:13:06

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>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:50
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>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 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 19:18:31

Generated On: 11 Aug 2021 22:13:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:13
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 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 19:18:31

Generated On: 11 Aug 2021 22:13:06

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: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:18:31

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Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 12:43 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 12:43

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 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:04 (24 HR)
Collection date and time (derived)	24 AUG 2020 12:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Collection date (<i>dd MMM yyyy</i>)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:02	24 AUG 2020 12:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

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: 11 Aug 2021 22:13:06

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 24 AUG 2020 13:03

PC Open Date & Time 24 AUG 2020 13:03

PC Close Date & Time 24 AUG 2020 15:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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** 98.6 °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 25 AUG 2020 10:29

PC Open Date & Time 24 AUG 2020 16:28

PC Close Date & Time 25 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 98.1 °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 26 AUG 2020 10:06

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

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	98.2 °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	27 AUG 2020 10:15
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

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

PC Time Stamp	28 AUG 2020 09:15
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

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** 97.8 °F

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

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

PC Time Stamp 29 AUG 2020 06:28

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 10:16
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F _____
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 30 AUG 2020 12:00
PC Close Date & Time 31 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

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

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

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

24 AUG 2020 13:04

PC Open Date & Time

24 AUG 2020 13:03

PC Close Date & Time

24 AUG 2020 15:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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	25 AUG 2020 09:52
PC Open Date & Time	24 AUG 2020 16:28
PC Close Date & Time	25 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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	26 AUG 2020 10:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	27 AUG 2020 10:15
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

28 AUG 2020 08:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

29 AUG 2020 06:28

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

30 AUG 2020 10:09

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

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

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

No

Yes

PC Time stamp	24 AUG 2020 13:04
PC Open Date & Time	24 AUG 2020 13:03
PC Close Date & Time	24 AUG 2020 15:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

No

Yes

PC Time stamp	25 AUG 2020 10:30
PC Open Date & Time	24 AUG 2020 16:28
PC Close Date & Time	25 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 10:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 10:16
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 09:16
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 06:29
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 10:09
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

Yes

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 21 SEP 2020

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

Folder OID VISIT2

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

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>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:43 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:43
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

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>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:44
Temperature (<i>xxx.x</i>)	97.3 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>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3302345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 21 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:14 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:14

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

US3302345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 21 SEP 2020

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

Collection date and time (derived) 21 SEP 2020 10:00

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Collection date (<i>dd MMM yyyy</i>)			21 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	09:58	21 SEP 2020 09:58
Nasopharyngeal Swab 2	Yes	09:58	21 SEP 2020 09:58

US3302345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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 97.3 °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 21 SEP 2020 10:34

PC Open Date & Time 21 SEP 2020 10:34

PC Close Date & Time 21 SEP 2020 13:04

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °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 22 SEP 2020 08:10
PC Open Date & Time 21 SEP 2020 13:59
PC Close Date & Time 22 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 23 SEP 2020 10:48

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °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	24 SEP 2020 09:16
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 09:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

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

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

PC Time Stamp	26 SEP 2020 06:33
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 07:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

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

PC Time Stamp	28 SEP 2020 06:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

21 SEP 2020 10:34

PC Open Date & Time

21 SEP 2020 10:34

PC Close Date & Time

21 SEP 2020 13:04

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

1

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

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

Please select one response below

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

PC Time Stamp 22 SEP 2020 08:10

PC Open Date & Time 21 SEP 2020 13:59

PC Close Date & Time 22 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

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

1

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)**

1

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

23 SEP 2020 10:48

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	24 SEP 2020 08:18
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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	25 SEP 2020 08:22
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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	26 SEP 2020 06:33
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

27 SEP 2020 07:16

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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	28 SEP 2020 06:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

No

Yes

PC Time stamp	21 SEP 2020 10:35
PC Open Date & Time	21 SEP 2020 10:34
PC Close Date & Time	21 SEP 2020 13:04

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

No

Yes

PC Time stamp	22 SEP 2020 08:12
PC Open Date & Time	21 SEP 2020 13:59
PC Close Date & Time	22 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 10:49
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 08:19
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 08:22
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 06:34
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 07:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 06:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted?

Yes

No

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

29 SEP 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 OCT 2020

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

Folder OID VISIT3

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 19 OCT 2020

Time of assessment (00:00-23:59) 09:50 (24 HR)

Vital Signs Date and Time (derived) 19 OCT 2020 09:50

Temperature (xxx.x) 98.7 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 85 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 112 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 83 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3302345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3302345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 19 OCT 2020

Collection time (*00:00-23:59*) 09:52 (24 HR)

Collection date and time (derived) 19 OCT 2020 09:52

US3302345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:32

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 06:30:46
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 08:18:01
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 07 NOV 2020 07:02:29

Patient Cloud Open Date & Time 07 NOV 2020 00:01

Patient Cloud Close Date & Time 11 NOV 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 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"/>

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 <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"/>

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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	09 DEC 2020 20:41:06
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 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	16 DEC 2020 08:01:04
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

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 23 DEC 2020 07:39:22

Patient Cloud Open Date & Time 23 DEC 2020 00:01

Patient Cloud Close Date & Time 27 DEC 2020 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	30 DEC 2020 13:13:35
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 138
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	06 JAN 2021 02:37:42
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 145

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 14 JAN 2021 08:30:08

Patient Cloud Open Date & Time 13 JAN 2021 00:01

Patient Cloud Close Date & Time 17 JAN 2021 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

DAY 152

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 20 JAN 2021 07:51:24

Patient Cloud Open Date & Time 20 JAN 2021 00:01

Patient Cloud Close Date & Time 24 JAN 2021 23:59

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT	DAY 159
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	27 JAN 2021 04:10:29
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3302345

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:13:06

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
<hr/>		
<hr/>		

US3302345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted?

Yes

No

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

17 DEC 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3302345

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3302345

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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 _____

US3302345

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3302345

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:06

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"/>

US3302345

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:13:06

Generate Next COVID-19 Assessment

Yes

No

US3302345

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 FEB 2021

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

Folder OID UNBLND_DECIDE

US3302345

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:34:17

Generated On: 11 Aug 2021 22:13:06

Date of updated informed consent (*dd MMM yyyy*) 2 FEB 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*) 02 FEB 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 _____

US3302345

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 FEB 2021

Collection time (*00:00-23:59*) 08:21 (24 HR)

Collection date and time (derived) 02 FEB 2021 08:21

US3302345

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	02 FEB 2021
Collection time (<i>00:00 - 23:59</i>)	08:18
Collection Date and Time (derived)	02 FEB 2021 08:18

US3302345

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

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

Yes

No

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

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

Name of Medication LEXAPRO

Prophylaxis Yes
No

Indication ANXIETY

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

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

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 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

Name of Medication LARIN FE

Prophylaxis Yes
No

Indication BIRTH CONTROL

Dose per administration 1/20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

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 2018

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

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

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

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:18:30

Generated On: 11 Aug 2021 22:13:06

	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*) 25 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 AUG 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

US3302345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:18:31

Generated On: 11 Aug 2021 22:13:06

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3302345

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 29 Apr 2021 12:34:17

Generated On: 11 Aug 2021 22:13:06

Date of study discontinuation/completion (dd MMM yyyy) 02 FEB 2021

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify _____

Date of death (dd MMM yyyy) _____

Was autopsy performed?

Yes

No

Unknown

Audit

US3302345 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302345

Form: Participant Creation

Generated On: 11 Aug 2021 22:13:06

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'US3302345'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 15:59:52

US3302345

Form: Participant Creation

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:14

US3302345

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 15:59:53

US3302345

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:14

US3302345

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'SCRN'	System	24 Aug 2020 16:18:14

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered (b) (6) 1994'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 15:59:54

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '26'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'YEARS'	System	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '26'	System	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Female (F)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '1'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:27

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'Aug 2020'	System	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '2020'	System	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 14:45:58
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:36

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 15:59:53

US3302345

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '1'	System	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:13:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:18:46

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:20:42
Data point term sent to Coder	System	24 Aug 2020 16:19:31
User entered 'anxiety'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'un UNK 2017'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'Jan 2017'	System	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '2017'	System	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered empty.	System	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered empty.	System	24 Aug 2020 16:19:00

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '11:50'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 11:50'	System	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '66' in	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:33
DataPoint set to visible.	System	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '125' lb	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:33
DataPoint set to visible.	System	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
Amendment Manager: User entered '20.21771'	System	17 Sep 2020 00:21:18
User entered '20.2'	System	24 Aug 2020 16:19:33
DataPoint set to visible.	System	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'kg/m2'	System	24 Aug 2020 16:19:33
DataPoint set to visible.	System	24 Aug 2020 16:18:40

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 06:15:35
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:40:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:01:11
User entered '97.7' F	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User entered '78'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'bpm'	System	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User entered '14'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'breaths/min'	System	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User entered '121'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:40:30
User entered '86'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	24 Aug 2020 16:19:33

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58

US3302345

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58

US3302345

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:39

US3302345

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:39

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:06

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:19:50

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4) (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Urine (URINE)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Negative (NEGATIVE)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered empty.	System	24 Aug 2020 16:20:04

US3302345

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

US3302345

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

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[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

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[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:57:59
User entered '1'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

US3302345

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

US3302345

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:57:59
User entered '0'	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

US3302345

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:20:27

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:04

US3302345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:47:04

US3302345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:04

US3302345

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'VISIT1'	System	24 Aug 2020 16:47:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '107743'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4) (b) (4)	24 Aug 2020 16:47:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4) [Redacted] [Redacted]	24 Aug 2020 16:47:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:16

US3302345

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:06

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
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 15:19:29
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 13:11:24
User entered 'No (N)'	(b) (4), (b) (6)	03 Dec 2020 13:11:18
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 19:12:21
DataPoint set to visible.	System	23 Oct 2020 14:45:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:39:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:39:55
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:39:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:01:17
User entered '66' in	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered '125' lb	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:39:55
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:39:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:01:17
User entered '66' in	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered '125' lb	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '11:50' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 11:50'	System	07 Oct 2020 14:39:46
User entered empty.	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '97.7' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '78' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'bpm'	System	07 Oct 2020 14:39:46
User entered empty.	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '14' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'breaths/min'	System	07 Oct 2020 14:39:46
User entered empty.	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '121' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	07 Oct 2020 14:39:46
User entered empty.	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '86' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	07 Oct 2020 14:39:46
User entered empty.	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:39:55
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 14:39:50
answered with 'done' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:01:17
User entered '66' in	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:39:46
User entered '125' lb	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '13:13'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 13:13'	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '97.7' F	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '82'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'bpm'	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '16'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'breaths/min'	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '126'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '81'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'mmHg'	System	24 Aug 2020 18:00:50

US3302345

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:54

US3302345

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:54

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered empty.	System	24 Aug 2020 18:00:59

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '12:43'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 12:43'	System	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4) (b) (4)	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'ONCE'	System	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 16:47:33

US3302345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:09

US3302345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:01:09

US3302345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '12:04'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:01:09

US3302345

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 12:04'	System	24 Aug 2020 18:01:09

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '24 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '12:02'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '24 Aug 2020 12:02'	System	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 18:49:48
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 18:49:48
User entered '12:02'	Brittany Belcher (b) (4)	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered empty.	System	20 Oct 2020 18:49:48
User entered '24 Aug 2020 12:02'	System	24 Aug 2020 18:01:21

US3302345

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 18:01:25

US3302345

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '1'	System	24 Aug 2020 18:01:25

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:03:33', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1d31b9c6-7829-4d87-bd6c-5de92eef48c6'	System	24 Aug 2020 17:03:53
User entered 'Yes (Y)'	System	24 Aug 2020 17:03:53

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:03:40', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1d31b9c6-7829-4d87-bd6c-5de92eef48c6'	System	24 Aug 2020 17:03:53
User entered '97.7'	System	24 Aug 2020 17:03:53

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:03:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1d31b9c6-7829-4d87-bd6c-5de92eef48c6'	System	24 Aug 2020 17:03:53
User entered 'No (N)'	System	24 Aug 2020 17:03:53

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:03:50', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1d31b9c6-7829-4d87-bd6c-5de92eef48c6'	System	24 Aug 2020 17:03:53
User entered '24 Aug 2020 13:03'	System	24 Aug 2020 17:03:53

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 13:03'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eeb9943ba32'	System	25 Aug 2020 14:29:57
User entered 'Yes (Y)'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:39', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eefb9943ba32'	System	25 Aug 2020 14:29:57
User entered '98.6'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eefb9943ba32'	System	25 Aug 2020 14:29:57
User entered 'Yes (Y)'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
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 15:18:05
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 17:31:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:49', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eefb9943ba32'	System	25 Aug 2020 14:29:57
User entered '1'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:49', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eefb9943ba32'	System	25 Aug 2020 14:29:57
User entered '0'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:52', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '01ac51ec-f864-40cb-b9b0-eefb9943ba32'	System	25 Aug 2020 14:29:57
User entered '25 Aug 2020 10:29'	System	25 Aug 2020 14:29:57

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 16:28'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 2'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:05:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered 'Yes (Y)'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:05:34', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered '98.1'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:05:39', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered 'Yes (Y)'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
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 15:18:09
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 17:31:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:05:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered '1'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:05:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered '0'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:06:21', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cc983c47-1194-4cf4-9f79-55ea49c49d37'	System	26 Aug 2020 14:06:23
User entered '26 Aug 2020 10:06'	System	26 Aug 2020 14:06:23

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 3'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f282ba-2bf3-402e-b310-ee122055035c'	System	27 Aug 2020 14:15:26
User entered 'Yes (Y)'	System	27 Aug 2020 14:15:26

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:17', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f282ba-2bf3-402e-b310-ee122055035c'	System	27 Aug 2020 14:15:26
User entered '98.2'	System	27 Aug 2020 14:15:26

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f282ba-2bf3-402e-b310-ee122055035c'	System	27 Aug 2020 14:15:26
User entered 'No (N)'	System	27 Aug 2020 14:15:26

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f282ba-2bf3-402e-b310-ee122055035c'	System	27 Aug 2020 14:15:26
User entered '27 Aug 2020 10:15'	System	27 Aug 2020 14:15:26

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 4'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:15:49', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1a4c2176-421a-4c13-851c-3dc08aa27a97'	System	28 Aug 2020 13:15:59
User entered 'Yes (Y)'	System	28 Aug 2020 13:15:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:15:53', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1a4c2176-421a-4c13-851c-3dc08aa27a97'	System	28 Aug 2020 13:15:59
User entered '98.0'	System	28 Aug 2020 13:15:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:15:55', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1a4c2176-421a-4c13-851c-3dc08aa27a97'	System	28 Aug 2020 13:15:59
User entered 'No (N)'	System	28 Aug 2020 13:15:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:15:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1a4c2176-421a-4c13-851c-3dc08aa27a97'	System	28 Aug 2020 13:15:59
User entered '28 Aug 2020 09:15'	System	28 Aug 2020 13:15:59

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 5'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:17', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c1e6e5e7-d235-47f4-bb7a-d9dc2b0ee5d6'	System	29 Aug 2020 10:28:31
User entered 'Yes (Y)'	System	29 Aug 2020 10:28:31

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:22', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c1e6e5e7-d235-47f4-bb7a-d9dc2b0ee5d6'	System	29 Aug 2020 10:28:31
User entered '97.8'	System	29 Aug 2020 10:28:31

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c1e6e5e7-d235-47f4-bb7a-d9dc2b0ee5d6'	System	29 Aug 2020 10:28:31
User entered 'No (N)'	System	29 Aug 2020 10:28:31

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c1e6e5e7-d235-47f4-bb7a-d9dc2b0ee5d6'	System	29 Aug 2020 10:28:31
User entered '29 Aug 2020 06:28'	System	29 Aug 2020 10:28:31

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 6'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:16:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'b5eb14d2-05c8-4a74-b937-25d1f0246aec'	System	30 Aug 2020 14:16:51
User entered 'Yes (Y)'	System	30 Aug 2020 14:16:51

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:16:37', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'b5eb14d2-05c8-4a74-b937-25d1f0246ac'	System	30 Aug 2020 14:16:51
User entered '97.8'	System	30 Aug 2020 14:16:51

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:16:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'b5eb14d2-05c8-4a74-b937-25d1f0246ac'	System	30 Aug 2020 14:16:51
User entered 'No (N)'	System	30 Aug 2020 14:16:51

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:16:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'b5eb14d2-05c8-4a74-b937-25d1f0246aec'	System	30 Aug 2020 14:16:51
User entered '30 Aug 2020 10:16'	System	30 Aug 2020 14:16:51

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 7'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'dc0e7ceb-2d2e-45df-bafb-b577156b57fe'	System	24 Aug 2020 17:04:17
User entered 'None (1)'	System	24 Aug 2020 17:04:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:05', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'dc0e7ceb-2d2e-45df-bafb-b577156b57fe'	System	24 Aug 2020 17:04:17
User entered 'No (N)'	System	24 Aug 2020 17:04:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'dc0e7ceb-2d2e-45df-bafb-b577156b57fe'	System	24 Aug 2020 17:04:17
User entered 'No (N)'	System	24 Aug 2020 17:04:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'dc0e7ceb-2d2e-45df-bafb-b577156b57fe'	System	24 Aug 2020 17:04:17
User entered 'None (1)'	System	24 Aug 2020 17:04:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:15', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'dc0e7ceb-2d2e-45df-bafb-b577156b57fe' User entered '24 Aug 2020 13:04'	System	24 Aug 2020 17:04:17
	System	24 Aug 2020 17:04:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '24 Aug 2020 13:03'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1 (at home) and Dose 2 Day 1 (at home), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:53:23
Query 'Per DM CLR: Per Diary Dose 1 Day 1 (at home) and Dose 2 Day 1 (at home), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Tylenol is listed in Con Meds.' (Site from DM).	Brittany Belcher (b) (4)	26 Feb 2021 21:09:55
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1 (at home) and Dose 2 Day 1 (at home), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity/Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 14:24:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T09:51:59', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '23f3d2db-4fb7-406c-8a06-ae84b040ff3'	System	25 Aug 2020 13:52:31
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	25 Aug 2020 13:52:31

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T09:52:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '23f3d2db-4fb7-406c-8a06-ace84b040ff3'	System	25 Aug 2020 13:52:31
User entered 'No (N)'	System	25 Aug 2020 13:52:31

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T09:52:19', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '23f3d2db-4fb7-406c-8a06-ace84b040ff3'	System	25 Aug 2020 13:52:31
User entered 'No (N)'	System	25 Aug 2020 13:52:31

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T09:52:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '23f3d2db-4fb7-406c-8a06-ae84b040ff3'	System	25 Aug 2020 13:52:31
User entered 'None (1)'	System	25 Aug 2020 13:52:31

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T09:52:27', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '23f3d2db-4fb7-406c-8a06-ae84b040ff3'	System	25 Aug 2020 13:52:31
User entered '25 Aug 2020 09:52'	System	25 Aug 2020 13:52:31

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '24 Aug 2020 16:28'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 2'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:06:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '937ff9f3-685e-44bb-86dd-024bf8279f1f'	System	26 Aug 2020 14:07:17
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 14:07:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '937ff9f3-685e-44bb-86dd-024bf8279f1f'	System	26 Aug 2020 14:07:17
User entered 'No (N)'	System	26 Aug 2020 14:07:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '937ff9f3-685e-44bb-86dd-024bf8279f1f'	System	26 Aug 2020 14:07:17
User entered 'No (N)'	System	26 Aug 2020 14:07:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:09', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '937ff9f3-685e-44bb-86dd-024bf8279f1f'	System	26 Aug 2020 14:07:17
User entered 'None (1)'	System	26 Aug 2020 14:07:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '937ff9f3-685e-44bb-86dd-024bf8279f1f' User entered '26 Aug 2020 10:07'	System	26 Aug 2020 14:07:17
	System	26 Aug 2020 14:07:17

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 3'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '69049c52-20a6-4ff5-8849-d3ba5b53e84a'	System	27 Aug 2020 14:15:51
User entered 'None (1)'	System	27 Aug 2020 14:15:51

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:39', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '69049c52-20a6-4ff5-8849-d3ba5b53e84a'	System	27 Aug 2020 14:15:51
User entered 'No (N)'	System	27 Aug 2020 14:15:51

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:42', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '69049c52-20a6-4ff5-8849-d3ba5b53e84a'	System	27 Aug 2020 14:15:51
User entered 'No (N)'	System	27 Aug 2020 14:15:51

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '69049c52-20a6-4ff5-8849-d3ba5b53e84a'	System	27 Aug 2020 14:15:51
User entered 'None (1)'	System	27 Aug 2020 14:15:51

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:15:48', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '69049c52-20a6-4ff5-8849-d3ba5b53e84a'	System	27 Aug 2020 14:15:51
User entered '27 Aug 2020 10:15'	System	27 Aug 2020 14:15:51

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 4'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T08:01:19', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ae1b9336-b573-401b-a792-01e3f5d6cf3c'	System	28 Aug 2020 12:01:34
User entered 'None (1)'	System	28 Aug 2020 12:01:34

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T08:01:22', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ae1b9336-b573-401b-a792-01e3f5d6cf3c'	System	28 Aug 2020 12:01:34
User entered 'No (N)'	System	28 Aug 2020 12:01:34

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T08:01:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ae1b9336-b573-401b-a792-01e3f5d6cf3c'	System	28 Aug 2020 12:01:34
User entered 'No (N)'	System	28 Aug 2020 12:01:34

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T08:01:28', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ae1b9336-b573-401b-a792-01e3f5d6cf3c'	System	28 Aug 2020 12:01:34
User entered 'None (1)'	System	28 Aug 2020 12:01:34

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T08:01:31', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ae1b9336-b573-401b-a792-01e3f5d6cf3c'	System	28 Aug 2020 12:01:34
User entered '28 Aug 2020 08:01'	System	28 Aug 2020 12:01:34

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 5'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '129eed33-9873-416d-9c02-e0d57ff5cd20'	System	29 Aug 2020 10:28:52
User entered 'None (1)'	System	29 Aug 2020 10:28:52

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:38', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '129eed33-9873-416d-9c02-e0d57ff5cd20'	System	29 Aug 2020 10:28:52
User entered 'No (N)'	System	29 Aug 2020 10:28:52

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '129eed33-9873-416d-9c02-e0d57ff5cd20'	System	29 Aug 2020 10:28:52
User entered 'No (N)'	System	29 Aug 2020 10:28:52

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '129eed33-9873-416d-9c02-e0d57ff5cd20'	System	29 Aug 2020 10:28:52
User entered 'None (1)'	System	29 Aug 2020 10:28:52

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '129eed33-9873-416d-9c02-e0d57ff5cd20'	System	29 Aug 2020 10:28:52
User entered '29 Aug 2020 06:28'	System	29 Aug 2020 10:28:52

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 6'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e2c8b90b-e5a0-47fc-8d3e-f075025edca4'	System	30 Aug 2020 14:09:43
User entered 'None (1)'	System	30 Aug 2020 14:09:43

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:30', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e2c8b90b-e5a0-47fc-8d3e-f075025edca4'	System	30 Aug 2020 14:09:43
User entered 'No (N)'	System	30 Aug 2020 14:09:43

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e2c8b90b-e5a0-47fc-8d3e-f075025edca4'	System	30 Aug 2020 14:09:43
User entered 'No (N)'	System	30 Aug 2020 14:09:43

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:34', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e2c8b90b-e5a0-47fc-8d3e-f075025edca4'	System	30 Aug 2020 14:09:43
User entered 'None (1)'	System	30 Aug 2020 14:09:43

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:36', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e2c8b90b-e5a0-47fc-8d3e-f075025edca4'	System	30 Aug 2020 14:09:43
User entered '30 Aug 2020 10:09'	System	30 Aug 2020 14:09:43

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 7'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:28:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:25', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:28', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:31', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:33', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:37', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'None (0)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered 'No (N)'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-24T13:04:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '99fef95e-cd98-4323-b8c2-708288ac1918'	System	24 Aug 2020 17:04:48
User entered '24 Aug 2020 13:04'	System	24 Aug 2020 17:04:48

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 13:03'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:29:57', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'None (0)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'Some interference with activity (2)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'Some interference with activity (2)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:07', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'None (0)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:15', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:18', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'None (0)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:25', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered 'No (N)'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-25T10:30:30', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd1a15ba-579d-4493-93df-a51700b94a91'	System	25 Aug 2020 14:30:33
User entered '25 Aug 2020 10:30'	System	25 Aug 2020 14:30:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Aug 2020 16:28'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 2'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf'	System	26 Aug 2020 14:07:51
User entered 'No interference with activity (1)'	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf'	System	26 Aug 2020 14:07:51
User entered 'No interference with activity (1)'	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:28', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf'	System	26 Aug 2020 14:07:51
User entered 'No interference with activity (1)'	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:31', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf' User entered 'None (0)'	System	26 Aug 2020 14:07:51
	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:36', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf'	System	26 Aug 2020 14:07:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:38', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf' User entered 'None (0)'	System	26 Aug 2020 14:07:51
	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf'	System	26 Aug 2020 14:07:51
User entered 'No (N)'	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-26T10:07:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '86aa0df9-7b05-403f-96e9-508bf4ac6cbf' User entered '26 Aug 2020 10:07'	System	26 Aug 2020 14:07:51
	System	26 Aug 2020 14:07:51

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 3'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'None (0)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:09', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'No interference with activity (1)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:15', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'None (0)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:17', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'None (0)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:19', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'None (0)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:21', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'None (0)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:23', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered 'No (N)'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-27T10:16:25', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0102ba7b-16ae-4839-8bb9-f3d410ff8889'	System	27 Aug 2020 14:16:31
User entered '27 Aug 2020 10:16'	System	27 Aug 2020 14:16:31

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 4'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'None (0)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:05', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'No interference with activity (1)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'None (0)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'None (0)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:09', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'None (0)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:11', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'None (0)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15'	System	28 Aug 2020 13:16:16
User entered 'No (N)'	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-28T09:16:14', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e3ca3b30-ecbc-4e69-86a2-1587d93c1e15' User entered '28 Aug 2020 09:16'	System	28 Aug 2020 13:16:16
	System	28 Aug 2020 13:16:16

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 5'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:52', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:54', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:57', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:28:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:29:00', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:29:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'None (0)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:29:05', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered 'No (N)'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-29T06:29:07', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '777a858d-89a6-4516-a031-be6a40591539'	System	29 Aug 2020 10:29:10
User entered '29 Aug 2020 06:29'	System	29 Aug 2020 10:29:10

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 6'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:48', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:50', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'None (0)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:53', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered 'No (N)'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-08-30T10:09:56', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '546d23eb-0db8-48ee-bf8c-02560c5cce72'	System	30 Aug 2020 14:10:03
User entered '30 Aug 2020 10:09'	System	30 Aug 2020 14:10:03

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 7'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:47:33

US3302345

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	01 Sep 2020 16:17:58

US3302345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '1 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	01 Sep 2020 16:17:58

US3302345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4) (b) (4)	01 Sep 2020 16:17:58

US3302345

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Wendy Taylor (b) (4)	01 Sep 2020 16:17:58

US3302345

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	01 Sep 2020 16:17:51

US3302345

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '1'	System	01 Sep 2020 16:17:51

US3302345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	09 Sep 2020 20:57:26

US3302345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '9 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	09 Sep 2020 20:57:26

US3302345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4) (b) (4)	09 Sep 2020 20:57:26

US3302345

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Wendy Taylor (b) (4)	09 Sep 2020 20:57:26

US3302345

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	09 Sep 2020 20:57:30

US3302345

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '1'	System	09 Sep 2020 20:57:30

US3302345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Sep 2020 19:25:19

US3302345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '14 Sep 2020'	(b) (4) brittany cooksey (b) (4)	14 Sep 2020 19:25:19
	(b) (4)	

US3302345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) brittany cooksey (b) (4)	14 Sep 2020 19:25:19
	(b) (4)	

US3302345

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) brittany cooksey (b) (4)	14 Sep 2020 19:25:19
	(b) (4)	

US3302345

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4)	14 Sep 2020 19:25:28

US3302345

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:58
User entered '1'	System	14 Sep 2020 19:25:28

US3302345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 14:17:00

US3302345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 14:17:00

US3302345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[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 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	21 Sep 2020 14:17:00

US3302345

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'VISIT2'	System	21 Sep 2020 14:17:00

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:31:05
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 18:00:40
User entered '09:43' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 18:00:35
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:20:51
User entered '9:43'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 09:43'	System	15 Oct 2020 18:00:35
User entered '21 Sep 2020 9:43'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '97.3' F	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '76'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'bpm'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '16'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'breaths/min'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '119'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '89'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '10:44'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 10:44'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '97.3' F	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '86'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'bpm'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '16'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'breaths/min'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '112'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '82'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	21 Sep 2020 15:05:05

US3302345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:11

US3302345

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:11

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Urine (URINE)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Negative (NEGATIVE)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered empty.	System	21 Sep 2020 15:05:33

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '10:14'	Brittany Belcher (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 10:14'	System	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4) (b) (4)	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'ONCE'	System	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:17:15

US3302345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:41

US3302345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:41

US3302345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '10:00'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:41

US3302345

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 10:00'	System	21 Sep 2020 15:05:41

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '21 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '09:58' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:01:04
User entered '9:58'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 09:58'	System	11 Nov 2020 16:01:04
User entered '21 Sep 2020 9:58'	System	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '09:58' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:01:04
User entered '9:58'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '21 Sep 2020 09:58'	System	11 Nov 2020 16:01:04
User entered '21 Sep 2020 9:58'	System	21 Sep 2020 15:05:53

US3302345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:05:56

US3302345

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	21 Sep 2020 15:05:56

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:07', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '04c08336-d1bc-4c1b-89c3-e2cddabde001'	System	21 Sep 2020 14:36:40
User entered 'Yes (Y)'	System	21 Sep 2020 14:36:40

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '04c08336-d1bc-4c1b-89c3-e2cddabde001'	System	21 Sep 2020 14:36:40
User entered '97.3'	System	21 Sep 2020 14:36:40

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '04c08336-d1bc-4c1b-89c3-e2cddabde001'	System	21 Sep 2020 14:36:40
User entered 'No (N)'	System	21 Sep 2020 14:36:40

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:18', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '04c08336-d1bc-4c1b-89c3-e2cddabde001'	System	21 Sep 2020 14:36:40
User entered '21 Sep 2020 10:34'	System	21 Sep 2020 14:36:40

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 10:34'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:04'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:09:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'f4cfafdb-f2c9-4d84-93df-47ca258217bb'	System	22 Sep 2020 12:10:15
User entered 'Yes (Y)'	System	22 Sep 2020 12:10:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:09:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'f4cfafdb-f2c9-4d84-93df-47ca258217bb'	System	22 Sep 2020 12:10:15
User entered '97.3'	System	22 Sep 2020 12:10:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:09:51', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'f4cfafdb-f2c9-4d84-93df-47ca258217bb'	System	22 Sep 2020 12:10:15
User entered 'No (N)'	System	22 Sep 2020 12:10:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'f4cfafdb-f2c9-4d84-93df-47ca258217bb'	System	22 Sep 2020 12:10:15
User entered '22 Sep 2020 08:10'	System	22 Sep 2020 12:10:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 2'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:10', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9d4a09a0-03fb-4c0e-a42c-bac53af6dc5e'	System	23 Sep 2020 14:48:38
User entered 'Yes (Y)'	System	23 Sep 2020 14:48:38

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:15', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9d4a09a0-03fb-4c0e-a42c-bac53af6dc5e'	System	23 Sep 2020 14:48:38
User entered '98.0'	System	23 Sep 2020 14:48:38

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:18', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9d4a09a0-03fb-4c0e-a42c-bac53af6dc5e'	System	23 Sep 2020 14:48:38
User entered 'No (N)'	System	23 Sep 2020 14:48:38

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9d4a09a0-03fb-4c0e-a42c-bac53af6dc5e'	System	23 Sep 2020 14:48:38
User entered '23 Sep 2020 10:48'	System	23 Sep 2020 14:48:38

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 3'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T09:16:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '2a82f3a2-8e4c-4927-856c-17caaccd294d'	System	25 Sep 2020 12:21:59
User entered 'Yes (Y)'	System	25 Sep 2020 12:21:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T09:16:53', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '2a82f3a2-8e4c-4927-856c-17caaccd294d'	System	25 Sep 2020 12:21:59
User entered '97.9'	System	25 Sep 2020 12:21:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T09:16:56', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '2a82f3a2-8e4c-4927-856c-17caaccd294d'	System	25 Sep 2020 12:21:59
User entered 'No (N)'	System	25 Sep 2020 12:21:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T09:16:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '2a82f3a2-8e4c-4927-856c-17caaccd294d'	System	25 Sep 2020 12:21:59
User entered '24 Sep 2020 09:16'	System	25 Sep 2020 12:21:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 4'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T09:01:27', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '4c5b9cd2-2d6d-45a5-bf45-2bd9f41a5531'	System	25 Sep 2020 13:01:52
User entered 'Yes (Y)'	System	25 Sep 2020 13:01:52

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T09:01:34', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '4c5b9cd2-2d6d-45a5-bf45-2bd9f41a5531'	System	25 Sep 2020 13:01:52
User entered '97.3'	System	25 Sep 2020 13:01:52

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T09:01:38', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '4c5b9cd2-2d6d-45a5-bf45-2bd9f41a5531'	System	25 Sep 2020 13:01:52
User entered 'No (N)'	System	25 Sep 2020 13:01:52

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T09:01:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '4c5b9cd2-2d6d-45a5-bf45-2bd9f41a5531'	System	25 Sep 2020 13:01:52
User entered '25 Sep 2020 09:01'	System	25 Sep 2020 13:01:52

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 5'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '878a342e-17df-4007-831e-765f32457a2e'	System	26 Sep 2020 12:33:30
User entered 'Yes (Y)'	System	26 Sep 2020 12:33:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '878a342e-17df-4007-831e-765f32457a2e' User entered '97.6'	System	26 Sep 2020 12:33:30
	System	26 Sep 2020 12:33:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '878a342e-17df-4007-831e-765f32457a2e'	System	26 Sep 2020 12:33:30
User entered 'No (N)'	System	26 Sep 2020 12:33:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '878a342e-17df-4007-831e-765f32457a2e' User entered '26 Sep 2020 06:33'	System	26 Sep 2020 12:33:30
	System	26 Sep 2020 12:33:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 6'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:15:42', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c741fdf7-dee9-4f19-8b32-0e193db8955e'	System	27 Sep 2020 13:15:59
User entered 'Yes (Y)'	System	27 Sep 2020 13:15:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:15:51', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c741fdf7-dee9-4f19-8b32-0e193db8955e'	System	27 Sep 2020 13:15:59
User entered '97.4'	System	27 Sep 2020 13:15:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:15:54', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c741fdf7-dee9-4f19-8b32-0e193db8955e'	System	27 Sep 2020 13:15:59
User entered 'No (N)'	System	27 Sep 2020 13:15:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:15:57', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c741fdf7-dee9-4f19-8b32-0e193db8955e'	System	27 Sep 2020 13:15:59
User entered '27 Sep 2020 07:15'	System	27 Sep 2020 13:15:59

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 7'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c222d4f9-ff29-4200-9ad3-7935ee22b98e'	System	28 Sep 2020 12:08:30
User entered 'Yes (Y)'	System	28 Sep 2020 12:08:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c222d4f9-ff29-4200-9ad3-7935ee22b98e' User entered '98.0'	System	28 Sep 2020 12:08:30
	System	28 Sep 2020 12:08:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:23', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c222d4f9-ff29-4200-9ad3-7935ee22b98e'	System	28 Sep 2020 12:08:30
User entered 'No (N)'	System	28 Sep 2020 12:08:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c222d4f9-ff29-4200-9ad3-7935ee22b98e'	System	28 Sep 2020 12:08:30
User entered '28 Sep 2020 06:08'	System	28 Sep 2020 12:08:30

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cfe5195d-4d96-4530-ac6f-135cc4366faa'	System	21 Sep 2020 14:36:41
User entered 'None (1)'	System	21 Sep 2020 14:36:41

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:27', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cfe5195d-4d96-4530-ac6f-135cc4366faa'	System	21 Sep 2020 14:36:41
User entered 'No (N)'	System	21 Sep 2020 14:36:41

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:30', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cfe5195d-4d96-4530-ac6f-135cc4366faa'	System	21 Sep 2020 14:36:41
User entered 'No (N)'	System	21 Sep 2020 14:36:41

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:33', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cfe5195d-4d96-4530-ac6f-135cc4366faa'	System	21 Sep 2020 14:36:41
User entered 'None (1)'	System	21 Sep 2020 14:36:41

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cfe5195d-4d96-4530-ac6f-135cc4366faa'	System	21 Sep 2020 14:36:41
User entered '21 Sep 2020 10:34'	System	21 Sep 2020 14:36:41

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 10:34'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:04'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:23', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered 'No (N)'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:25', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered 'Yes (Y)'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered '1'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered 'None (1)'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:48', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df4d6f27-e4b9-493f-b31e-2916f4947f06'	System	22 Sep 2020 12:10:51
User entered '22 Sep 2020 08:10'	System	22 Sep 2020 12:10:51

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 2'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed'	System	23 Sep 2020 14:48:50
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed'	System	23 Sep 2020 14:48:50
User entered 'Yes (Y)'	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed' User entered '1'	System	23 Sep 2020 14:48:50
	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed'	System	23 Sep 2020 14:48:50
User entered 'Yes (Y)'	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:40', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed' User entered '1'	System	23 Sep 2020 14:48:50
	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:42', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed'	System	23 Sep 2020 14:48:50
User entered 'None (1)'	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ff382553-ea51-4bef-88ae-90c169bb86ed'	System	23 Sep 2020 14:48:50
User entered '23 Sep 2020 10:48'	System	23 Sep 2020 14:48:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 3'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:18:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '91ce72f5-b052-42e2-88c4-9b48213db3f5'	System	24 Sep 2020 12:19:01
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 12:19:01

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:18:39', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '91ce72f5-b052-42e2-88c4-9b48213db3f5'	System	24 Sep 2020 12:19:01
User entered 'No (N)'	System	24 Sep 2020 12:19:01

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:18:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '91ce72f5-b052-42e2-88c4-9b48213db3f5'	System	24 Sep 2020 12:19:01
User entered 'No (N)'	System	24 Sep 2020 12:19:01

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:18:49', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '91ce72f5-b052-42e2-88c4-9b48213db3f5'	System	24 Sep 2020 12:19:01
User entered 'None (1)'	System	24 Sep 2020 12:19:01

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:18:56', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '91ce72f5-b052-42e2-88c4-9b48213db3f5'	System	24 Sep 2020 12:19:01
User entered '24 Sep 2020 08:18'	System	24 Sep 2020 12:19:01

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 4'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '22e25599-36a7-465e-9a42-101e424f371d'	System	25 Sep 2020 12:22:15
User entered 'None (1)'	System	25 Sep 2020 12:22:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '22e25599-36a7-465e-9a42-101e424f371d'	System	25 Sep 2020 12:22:15
User entered 'No (N)'	System	25 Sep 2020 12:22:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '22e25599-36a7-465e-9a42-101e424f371d'	System	25 Sep 2020 12:22:15
User entered 'No (N)'	System	25 Sep 2020 12:22:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:11', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '22e25599-36a7-465e-9a42-101e424f371d'	System	25 Sep 2020 12:22:15
User entered 'None (1)'	System	25 Sep 2020 12:22:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '22e25599-36a7-465e-9a42-101e424f371d' User entered '25 Sep 2020 08:22'	System	25 Sep 2020 12:22:15
	System	25 Sep 2020 12:22:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 5'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ab1b6ed2-89d6-4f1e-b98e-9939bfc71ff2'	System	26 Sep 2020 12:33:50
User entered 'None (1)'	System	26 Sep 2020 12:33:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ab1b6ed2-89d6-4f1e-b98e-9939bfc71ff2'	System	26 Sep 2020 12:33:50
User entered 'No (N)'	System	26 Sep 2020 12:33:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ab1b6ed2-89d6-4f1e-b98e-9939bfc71ff2'	System	26 Sep 2020 12:33:50
User entered 'No (N)'	System	26 Sep 2020 12:33:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ab1b6ed2-89d6-4f1e-b98e-9939bfc71ff2'	System	26 Sep 2020 12:33:50
User entered 'None (1)'	System	26 Sep 2020 12:33:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:48', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ab1b6ed2-89d6-4f1e-b98e-9939bfc71ff2'	System	26 Sep 2020 12:33:50
User entered '26 Sep 2020 06:33'	System	26 Sep 2020 12:33:50

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 6'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'bd93af35-8d67-4516-8af4-bd82ca3b2429'	System	27 Sep 2020 13:16:14
User entered 'None (1)'	System	27 Sep 2020 13:16:14

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:05', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'bd93af35-8d67-4516-8af4-bd82ca3b2429'	System	27 Sep 2020 13:16:14
User entered 'No (N)'	System	27 Sep 2020 13:16:14

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'bd93af35-8d67-4516-8af4-bd82ca3b2429'	System	27 Sep 2020 13:16:14
User entered 'No (N)'	System	27 Sep 2020 13:16:14

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:10', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'bd93af35-8d67-4516-8af4-bd82ca3b2429'	System	27 Sep 2020 13:16:14
User entered 'None (1)'	System	27 Sep 2020 13:16:14

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:13', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'bd93af35-8d67-4516-8af4-bd82ca3b2429'	System	27 Sep 2020 13:16:14
User entered '27 Sep 2020 07:16'	System	27 Sep 2020 13:16:14

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 7'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ac0fa11c-406b-4cb8-b12f-0e03b9f184ac'	System	28 Sep 2020 12:08:37
User entered 'None (1)'	System	28 Sep 2020 12:08:37

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:30', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ac0fa11c-406b-4cb8-b12f-0e03b9f184ac'	System	28 Sep 2020 12:08:37
User entered 'No (N)'	System	28 Sep 2020 12:08:37

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ac0fa11c-406b-4cb8-b12f-0e03b9f184ac'	System	28 Sep 2020 12:08:37
User entered 'No (N)'	System	28 Sep 2020 12:08:37

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:33', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ac0fa11c-406b-4cb8-b12f-0e03b9f184ac'	System	28 Sep 2020 12:08:37
User entered 'None (1)'	System	28 Sep 2020 12:08:37

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ac0fa11c-406b-4cb8-b12f-0e03b9f184ac'	System	28 Sep 2020 12:08:37
User entered '28 Sep 2020 06:08'	System	28 Sep 2020 12:08:37

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:34:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'No interference with activity (1)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'None (0)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:03', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'None (0)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'None (0)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'None (0)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'None (0)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:10', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered 'No (N)'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-21T10:35:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '07a0e266-525b-47d5-b4b6-88c0931d8242'	System	21 Sep 2020 14:36:44
User entered '21 Sep 2020 10:35'	System	21 Sep 2020 14:36:44

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 10:34'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:04'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:55', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'No interference with activity (1)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:10:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'No interference with activity (1)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:11:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'No interference with activity (1)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:11:10', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'None (0)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:11:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'None (0)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:11:18', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'None (0)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:11:21', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered 'No (N)'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-22T08:12:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '79aa7751-b3df-4c00-9960-7171b5dcf444'	System	22 Sep 2020 12:12:12
User entered '22 Sep 2020 08:12'	System	22 Sep 2020 12:12:12

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '21 Sep 2020 13:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 2'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:48', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:49', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:51', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:52', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:54', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:48:56', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'None (0)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:49:00', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered 'No (N)'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-23T10:49:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '1e525cd7-047e-40a4-b50d-7f5d03531d2d'	System	23 Sep 2020 14:49:06
User entered '23 Sep 2020 10:49'	System	23 Sep 2020 14:49:06

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 3'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:09', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'None (0)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:12', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'None (0)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:14', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'None (0)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:17', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered 'No (N)'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-24T08:19:19', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'df0b2423-cc30-44e0-b2ea-d752fee0415c'	System	24 Sep 2020 12:19:23
User entered '24 Sep 2020 08:19'	System	24 Sep 2020 12:19:23

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 4'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'None (0)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:18', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'None (0)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:22', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'None (0)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:23', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'None (0)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'None (0)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:27', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered 'No (N)'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-25T08:22:28', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '65d1ef09-8fec-4f68-8056-2f177ddf1b65'	System	25 Sep 2020 12:22:33
User entered '25 Sep 2020 08:22'	System	25 Sep 2020 12:22:33

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 5'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User closed query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:47:35
Query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'no changes reported er subject' (Site from DM).	brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:38:07
User opened query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 16:41:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:33:59', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'No interference with activity (1)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'None (0)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'None (0)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'None (0)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:10', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'None (0)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:14', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered 'No (N)'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-26T06:34:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'ec2f33ef-4aac-4ce3-91c2-1bbe964f8931'	System	26 Sep 2020 12:34:18
User entered '26 Sep 2020 06:34'	System	26 Sep 2020 12:34:18

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 6'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:30', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:36', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:38', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'None (0)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered 'No (N)'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-27T07:16:43', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'e566fedd-38f6-4170-9c89-6bc7ec34ae30'	System	27 Sep 2020 13:16:45
User entered '27 Sep 2020 07:16'	System	27 Sep 2020 13:16:45

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	21 Sep 2020 14:17:15
User entered 'Day 7'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:38', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:39', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:40', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:41', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:42', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:44', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'None (0)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

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 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered 'No (N)'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-09-28T06:08:47', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '9f1b7060-8b7e-4c2d-ab58-cbe3d2d5cdc3'	System	28 Sep 2020 12:08:51
User entered '28 Sep 2020 06:08'	System	28 Sep 2020 12:08:51

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:17:15

US3302345

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:17:15

US3302345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	29 Sep 2020 16:50:33

US3302345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '29 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	29 Sep 2020 16:50:33

US3302345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	29 Sep 2020 16:50:33

US3302345

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Wendy Taylor (b) (4)	29 Sep 2020 16:50:33

US3302345

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	29 Sep 2020 16:50:26

US3302345

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	29 Sep 2020 16:50:26

US3302345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:23

US3302345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:23

US3302345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:23

US3302345

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:23

US3302345

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:41:28

US3302345

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	06 Oct 2020 15:41:28

US3302345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:09

US3302345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:09

US3302345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:09

US3302345

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:09

US3302345

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:14

US3302345

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	13 Oct 2020 14:36:14

US3302345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:49:23

US3302345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '19 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:49:23

US3302345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[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 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:49:23

US3302345

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'VISIT3'	System	19 Oct 2020 14:49:23

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '19 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '09:50'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '19 Oct 2020 09:50'	System	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '98.7' F	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (Oral)'	Brittany Belcher (b) (4) (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '85'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'bpm'	System	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '16'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'breaths/min'	System	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '112'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '83'	Brittany Belcher (b) (4)	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered 'mmHg'	System	19 Oct 2020 14:49:44

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15

US3302345

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15

US3302345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:50:05

US3302345

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '19 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:50:05

US3302345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 14:50:16

US3302345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 14:50:16

US3302345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:18:32
User entered '09:52'	Brittany Belcher (b) (4)	19 Oct 2020 14:50:16

US3302345

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '19 Oct 2020 09:52'	System	19 Oct 2020 14:50:16

US3302345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	19 Oct 2020 14:50:19

US3302345

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	19 Oct 2020 14:50:19

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 64'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-24T06:30:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '3001f45b-bc5a-4000-bd60-4bc6f89b6a60'	System	24 Oct 2020 10:30:47
User entered 'No (N)'	System	24 Oct 2020 10:30:47

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-24T06:30:40', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '3001f45b-bc5a-4000-bd60-4bc6f89b6a60'	System	24 Oct 2020 10:30:47
User entered 'No (N)'	System	24 Oct 2020 10:30:47

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-24T06:30:46', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '3001f45b-bc5a-4000-bd60-4bc6f89b6a60' User entered '24 Oct 2020 06:30:46'	System	24 Oct 2020 10:30:47
	System	24 Oct 2020 10:30:47

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 71'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-31T08:17:50', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '427bc9de-0737-4695-ab42-e3d11e40b316'	System	31 Oct 2020 12:18:05
User entered 'No (N)'	System	31 Oct 2020 12:18:05

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-31T08:17:57', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '427bc9de-0737-4695-ab42-e3d11e40b316'	System	31 Oct 2020 12:18:05
User entered 'No (N)'	System	31 Oct 2020 12:18:05

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-10-31T08:18:01', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '427bc9de-0737-4695-ab42-e3d11e40b316'	System	31 Oct 2020 12:18:05
User entered '31 Oct 2020 08:18:01'	System	31 Oct 2020 12:18:05

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered 'Day 78'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-11-07T07:02:21', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5ccbf2e6-ce1a-478b-988f-771649414dd8'	System	07 Nov 2020 12:02:35
User entered 'No (N)'	System	07 Nov 2020 12:02:35

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-11-07T07:02:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5ccbf2e6-ce1a-478b-988f-771649414dd8'	System	07 Nov 2020 12:02:35
User entered 'No (N)'	System	07 Nov 2020 12:02:35

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-11-07T07:02:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5ccbf2e6-ce1a-478b-988f-771649414dd8'	System	07 Nov 2020 12:02:35
User entered '07 Nov 2020 07:02:29'	System	07 Nov 2020 12:02:35

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 16:47:33

US3302345

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:42:28
Data entry locked.	System	24 Aug 2020 16:47:33
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 16:47:33

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-09T20:40:58', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd19d789-2fe3-410d-8ac6-bbf1682ef78d'	System	16 Dec 2020 13:00:54
User entered 'No (N)'	System	16 Dec 2020 13:00:54

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-09T20:41:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd19d789-2fe3-410d-8ac6-bbf1682ef78d'	System	16 Dec 2020 13:00:54
User entered 'No (N)'	System	16 Dec 2020 13:00:54

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-09T20:41:06', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'cd19d789-2fe3-410d-8ac6-bbf1682ef78d' User entered '09 Dec 2020 20:41:06'	System	16 Dec 2020 13:00:54
	System	16 Dec 2020 13:00:54

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-16T08:00:56', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c72decd2-7fb2-4025-b93a-338e7c2875f6'	System	16 Dec 2020 13:01:08
User entered 'No (N)'	System	16 Dec 2020 13:01:08

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-16T08:01:02', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c72decd2-7fb2-4025-b93a-338e7c2875f6'	System	16 Dec 2020 13:01:08
User entered 'No (N)'	System	16 Dec 2020 13:01:08

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-16T08:01:04', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'c72decd2-7fb2-4025-b93a-338e7c2875f6'	System	16 Dec 2020 13:01:08
User entered '16 Dec 2020 08:01:04'	System	16 Dec 2020 13:01:08

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-23T07:39:17', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f2d518-577b-4399-a0da-aef593fdf470'	System	23 Dec 2020 12:39:25
User entered 'No (N)'	System	23 Dec 2020 12:39:25

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-23T07:39:20', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f2d518-577b-4399-a0da-aef593fdf470'	System	23 Dec 2020 12:39:25
User entered 'No (N)'	System	23 Dec 2020 12:39:25

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-23T07:39:22', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '36f2d518-577b-4399-a0da-aef593fdf470' User entered '23 Dec 2020 07:39:22'	System	23 Dec 2020 12:39:25
	System	23 Dec 2020 12:39:25

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-30T13:13:32', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0b8d5751-688f-4e5d-a9cf-5063ac255b2f'	System	30 Dec 2020 18:13:37
User entered 'No (N)'	System	30 Dec 2020 18:13:37

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-30T13:13:33', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0b8d5751-688f-4e5d-a9cf-5063ac255b2f'	System	30 Dec 2020 18:13:37
User entered 'No (N)'	System	30 Dec 2020 18:13:37

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2020-12-30T13:13:35', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '0b8d5751-688f-4e5d-a9cf-5063ac255b2f' User entered '30 Dec 2020 13:13:35'	System	30 Dec 2020 18:13:37
	System	30 Dec 2020 18:13:37

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-06T02:37:37', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '8f5d5bbd-18d8-4968-af23-cbdc73f14042'	System	06 Jan 2021 07:37:47
User entered 'No (N)'	System	06 Jan 2021 07:37:47

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-06T02:37:40', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '8f5d5bbd-18d8-4968-af23-cbdc73f14042'	System	06 Jan 2021 07:37:47
User entered 'No (N)'	System	06 Jan 2021 07:37:47

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-06T02:37:42', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '8f5d5bbd-18d8-4968-af23-cbdc73f14042'	System	06 Jan 2021 07:37:47
User entered '06 Jan 2021 02:37:42'	System	06 Jan 2021 07:37:47

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-14T08:30:03', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5bd10929-e684-4eb0-9db9-ff33ff9fef0a'	System	14 Jan 2021 13:30:10
User entered 'No (N)'	System	14 Jan 2021 13:30:10

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-14T08:30:05', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5bd10929-e684-4eb0-9db9-ff33ff9fef0a'	System	14 Jan 2021 13:30:10
User entered 'No (N)'	System	14 Jan 2021 13:30:10

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-14T08:30:08', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: '5bd10929-e684-4eb0-9db9-ff33ff9fef0a' User entered '14 Jan 2021 08:30:08'	System	14 Jan 2021 13:30:10
	System	14 Jan 2021 13:30:10

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-20T07:51:16', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'abab91fe-927d-4b9b-9f7d-d0586ce989ec'	System	20 Jan 2021 12:51:28
User entered 'No (N)'	System	20 Jan 2021 12:51:28

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-20T07:51:22', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'abab91fe-927d-4b9b-9f7d-d0586ce989ec'	System	20 Jan 2021 12:51:28
User entered 'No (N)'	System	20 Jan 2021 12:51:28

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-20T07:51:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'abab91fe-927d-4b9b-9f7d-d0586ce989ec' User entered '20 Jan 2021 07:51:24'	System	20 Jan 2021 12:51:28
	System	20 Jan 2021 12:51:28

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-27T04:10:24', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'a0c1e700-abea-428e-81ff-4f6526dee845'	System	27 Jan 2021 09:10:34
User entered 'No (N)'	System	27 Jan 2021 09:10:34

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

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 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-27T04:10:26', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'a0c1e700-abea-428e-81ff-4f6526dee845'	System	27 Jan 2021 09:10:34
User entered 'No (N)'	System	27 Jan 2021 09:10:34

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c160d04199764b44)', Time: '2021-01-27T04:10:29', User OID: 'PatientReportedOutcome (US3302345)', ODM File OID: 'a0c1e700-abea-428e-81ff-4f6526dee845'	System	27 Jan 2021 09:10:34
User entered '27 Jan 2021 04:10:29'	System	27 Jan 2021 09:10:34

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:44:46

US3302345

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:46
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:44:46

US3302345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:17:09

US3302345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:17:09

US3302345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:17:09

US3302345

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:17:09

US3302345

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:17:12

US3302345

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:40:15
User entered '1'	System	19 Nov 2020 18:17:12

US3302345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:21:22

US3302345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:21:22

US3302345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:21:22

US3302345

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:21:22

US3302345

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:21:27

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Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:03
User entered '1'	System	17 Dec 2020 18:21:27

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	18 Jan 2021 17:10:22

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '18 Jan 2021'	Kendal Nelson (b) (4)	18 Jan 2021 17:10:22

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	18 Jan 2021 17:10:22

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Kendal Nelson (b) (4)	18 Jan 2021 17:10:22
	(b) (4)	

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Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	18 Jan 2021 17:10:14

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Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:10
User entered '1'	System	18 Jan 2021 17:10:14

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:25

US3302345

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:25

US3302345

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[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 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:25

US3302345

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 18:06:25

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[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 12:34:17
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 14:50:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:47:55

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:17
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
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 08:42:35
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 14:51:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brittany Belcher (b) (4)	12 Apr 2021 14:50:44
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 17:18:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:47:55

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User entered empty.	System	02 Feb 2021 18:06:40

US3302345

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User entered empty.	System	02 Feb 2021 18:06:40

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:49

US3302345

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:49

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '08:21'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:49

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:01
User entered '02 Feb 2021 08:21'	System	02 Feb 2021 18:06:49

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:05:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:00

US3302345

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:05:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:00

US3302345

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:05:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '08:18'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:00

US3302345

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:05:50
User entered '02 Feb 2021 08:18'	System	02 Feb 2021 18:07:00

US3302345

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	02 Feb 2021 18:13:08
User entered 'Yes (Y)'	(b) (4)	
	marsha gossett (b) (4)	02 Feb 2021 18:12:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:13:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:20:48

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 16:22:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 16:22:36
Data point term sent to Coder	System	24 Aug 2020 16:21:43
User entered 'lexapro'	Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'anxiety'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '10'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mg (mg)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'once daily (QD)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (ORAL)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'un UNK 2020'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '1'	System	24 Aug 2020 16:21:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '1'	System	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '804 (804)'	System	24 Aug 2020 16:21:16

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LARIN FE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Sep 2020 10:12:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Sep 2020 10:12:45
Data point term sent to Coder	System	01 Sep 2020 19:36:55
User closed query 'CDM Coding: This verbatim appears to be incomplete. Please report the complete trade name/active ingredients. Please make your changes to the reported term. Thank you.' (Site from System).	System	01 Sep 2020 19:36:43
Query 'CDM Coding: This verbatim appears to be incomplete. Please report the complete trade name/active ingredients. Please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	brittany cooksey (b) (4)	01 Sep 2020 19:36:43
User entered 'LARIN Fe' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Sep 2020 19:36:26
User opened query 'CDM Coding: This verbatim appears to be incomplete. Please report the complete trade name/active ingredients. Please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 10:50:39
Data point term sent to Coder	System	24 Aug 2020 16:21:44
User entered 'larin'	Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'birth control'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '1/20'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mg (mg)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'once daily (QD)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (ORAL)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'un UNK 2018'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '1'	System	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '1'	System	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User entered '804 (804)'	System	24 Aug 2020 16:21:43

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
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 19:42:24
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 19:42:24
Data point term sent to Coder User entered 'Tylenol'	System	28 Oct 2020 17:33:10
	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
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 SITE 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 SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 08:50:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE 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 SITE PAIN did not meet the AE reporting criteria.' answered with 'entered As reported per subject. This does not meet AE reporting criteria since within post 7 days vaccine.' (Site from DM).	brittany cooksey (b) (4) (b) (4)	26 Jan 2021 16:16:06

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[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 SITE 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 SITE PAIN did not meet the AE reporting criteria.' (Site from DM). User entered 'injection pain'	(b) (4), (b) (6) [REDACTED]	26 Jan 2021 09:42:36
	Brittany Belcher (b) (4) [REDACTED]	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '500'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'mg (mg)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '25 Aug 2020'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '0'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per DM CLR: Please verify end date as Pain at Injection Site is recorded with Grade 0 on 26 Aug 2020 in eDiary. Update the eCRF as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:51:00
Query 'Per DM CLR: Please verify end date as Pain at Injection Site is recorded with Grade 0 on 26 Aug 2020 in eDiary. Update the eCRF as appropriate or provide explanation.' answered with 'stopped as of 26AUG2020' (Site from DM).	brittany cooksey (b) (4)	26 Jan 2021 16:17:09
User opened query 'Per DM CLR: Please verify end date as Pain at Injection Site is recorded with Grade 0 on 26 Aug 2020 in eDiary. Update the eCRF as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:42:16
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in eDiary 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)	27 Jan 2021 08:50:57
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in eDiary 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)	26 Jan 2021 16:16:25
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	26 Jan 2021 16:16:15
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in eDiary 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)	26 Jan 2021 09:41:59
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User entered empty.	System	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User entered empty.	System	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:39
User entered empty.	System	28 Oct 2020 17:32:35

US3302345

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:13:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	24 Aug 2020 16:21:49

US3302345

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered '02 Feb 2021'	marsha gossett (b) (4)	02 Feb 2021 18:11:38

US3302345

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:06

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:17
Signature has been broken.	(b) (4) Brittany Belcher (b) (4)	19 Apr 2021 12:20:41
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	19 Apr 2021 12:20:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	02 Feb 2021 18:11:57
User entered 'Other (OTHER)' reason for change: Data Entry Error	marsha gossett (b) (4)	02 Feb 2021 18:11:57
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	02 Feb 2021 18:11:38
User entered 'Pregnancy (PREGNANCY)'	marsha gossett (b) (4)	02 Feb 2021 18:11:38

US3302345

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:06

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)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:17
User closed query 'Per CDM: As the specification listed under "Other, specify" is pregnancy, the Reason for Discontinuation must be updated from Other to Pregnancy.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 04:03:56
Query 'Per CDM: As the specification listed under "Other, specify" is pregnancy, the Reason for Discontinuation must be updated from Other to Pregnancy.' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	19 Apr 2021 12:20:53
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	19 Apr 2021 12:20:48
Signature has been broken.	Brittany Belcher (b) (4)	19 Apr 2021 12:20:48
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	19 Apr 2021 12:20:48
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 Apr 2021 12:20:41
User opened query 'Per CDM: As the specification listed under "Other, specify" is pregnancy, the Reason for Discontinuation must be updated from Other to Pregnancy.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 16:15:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
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).	(b) (4) System	02 Feb 2021 18:12:08

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

Audit	User	Time (GMT)
User entered 'pregnancy' reason for change: Data Entry Error	marsha gossett (b) (4) (b) (4)	02 Feb 2021 18:12:08
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	02 Feb 2021 18:11:57
User entered empty.	marsha gossett (b) (4) (b) (4)	02 Feb 2021 18:11:38

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty; reason for change Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	02 Feb 2021 18:11:57
User entered 'Other (OTHER)'	(b) (4)	
	marsha gossett (b) (4)	02 Feb 2021 18:11:38
	(b) (4)	

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If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User closed query 'Main cause of death is Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	02 Feb 2021 18:11:57
User opened query 'Main cause of death is Other, however specify is missing. Please provide.' (Site from System).	System	02 Feb 2021 18:11:38
User entered empty.	marsha gossett (b) (4) (b) (4)	02 Feb 2021 18:11:38

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Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	(b) (4) marsha gossett (b) (4)	02 Feb 2021 18:11:38

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:06

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:24:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:18:32
User entered empty.	marsha gossett (b) (4)	02 Feb 2021 18:11:38