

US3342259 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

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US3342259

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

[Participant ID](#)

US3342259

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

US3342259

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 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) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:18:31

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Date of Informed Consent (dd MMM yyyy)	14 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:18:31

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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) 12 Mar 2021 23:18:31

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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) 12 Mar 2021 23:18:31

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:21
Height (<i>xxx.x</i>)	189.5 cm
Weight (<i>xxx.x</i>)	100.9 kg
BMI (<i>xxx.x</i>)	28.09783 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:31

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:31

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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) 12 Mar 2021 23:18:31

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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) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

What was the date of randomization? (dd MMM yyyy) 14 SEP 2020

What was the participant's randomization number? 113649

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) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

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) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:21
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:39
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:31

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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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 13:04 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 13:04

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

12:49 (24 HR)

Collection date and time (derived)

14 SEP 2020 12:49

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:51	14 SEP 2020 12:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 13:44

PC Open Date & Time

14 SEP 2020 13:24

PC Close Date & Time

14 SEP 2020 15:54

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 16:49

PC Close Date & Time

15 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 11:48

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:37

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 10:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:44

PC Open Date & Time

14 SEP 2020 13:24

PC Close Date & Time

14 SEP 2020 15:54

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 16:49

PC Close Date & Time

15 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 11:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:39

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 10:43

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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 ☐

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 13:45
PC Open Date & Time	14 SEP 2020 13:24
PC Close Date & Time	14 SEP 2020 15:54

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 ☐

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 16:49

PC Close Date & Time

15 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

Yes ☐	
PC Time stamp	16 SEP 2020 11:49
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

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 ☒

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

Yes ☐	
PC Time stamp	17 SEP 2020 12:39
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

Yes ☐	
PC Time stamp	21 SEP 2020 10:44
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

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

US3342259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

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

US3342259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☒
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:32

Generated On: 09 Jun 2021 17:07:18

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:07:18

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

US3342259

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:07:18

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

US3342259

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:07:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342259

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3342259

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:18

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	☐
	No	☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5	☐
	Amendment 6 or later	☐
Date of unblinding (<i>dd MMM yyyy</i>)		
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		

US3342259

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3342259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:18

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3342259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

AEID

Adverse event MIGRAINE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

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

Start date (dd MMM yyyy) 14 SEP 2020

Start time (00:00-23:59) 20:00 (24 HR)

AE start date and time (derived) 14 SEP 2020 20:00

Ongoing? Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT REPORTED INTERMITTENT MIGRAINES STARTING 14 SEP 2020 AT 20:00 AND CONTINUING TO TODAY 16 OCT 2020. PATIENT DID NOT SEEK MEDICAL ATTENTION AND IS NOT ON MEDICATION.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

AEID

Adverse event

DEPRESSION WITH SUICIDAL
IDEATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☒ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUICIDAL IDEATION - PATIENT WENT TO HOSPITAL, SAW A DOCTOR BUT WAS NOT ADMITTED AND RECEIVED NO MEDICATION. PATIENT LET HOSPITAL SAME DAY. PLANS TO SEEK ADDITIONAL HELP.

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

AEID

Adverse event

ACUTE PHARYNGITIS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 SEP 2020

Start time (00:00-23:59)

19:00 (24 HR)

AE start date and time (derived)

14 SEP 2020 19:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 SEP 2020

End time (00:00-23:59)

20:00 (24 HR)

AE End Date and Time (derived)

14 SEP 2020 20:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 23:18:30

Generated On: 09 Jun 2021 17:07:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT REPORTED SORE THROAT FOLLOWING FIRST VACCINATION ON 14 SEP 2020 AT 19:00 HOURS. PATIENT DID NOT TAKE ANY MEDICATIONS AND SYMPTOMS RESOLVED WITHIN 24 HOURS.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 23:18:30

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Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

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

Yes ☒

No ☐

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

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Name of Medication VYVANSE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3342259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Date of dosing discontinuation (dd MMM yyyy)	16 OCT 2020
--	-------------

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #2
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US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:18:31

Generated On: 09 Jun 2021 17:07:18

Date of study discontinuation/completion (dd MMM yyyy) 16 OCT 2020

Reason for discontinuation

AE (specify) ☒

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

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

US3342259 (Prod: Tekton Research- Austin)

US3342259

Form: Participant Creation

Generated On: 09 Jun 2021 17:07:18

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:15:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'US3342259'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:14:40

US3342259

Form: Participant Creation

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

US3342259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:14:41

US3342259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'SCRN'	System	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered (b) (6) 1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:14:42

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '41'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'YEARS'	System	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '41'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Male (M)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '1'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'Sep 2020'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '2020'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Amendment 3 (3)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:14:41

US3342259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '1'	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:07:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:45:38

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 17:47:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 17:47:52
Data point term sent to Coder	System	14 Sep 2020 17:47:07
User entered 'INSOMNIA'	Morgan Schulle (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	15 Sep 2020 14:39:22
User entered 'un Jan 2020' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:22
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	14 Sep 2020 17:46:17
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 14:39:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 14:39:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Sep 2020 17:46:17
User entered empty.	System	14 Sep 2020 17:46:17
	Morgan Schulle (b) (4)	14 Sep 2020 17:46:17
	(b) (4)	

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'Jan 2020'	System	15 Sep 2020 14:39:22
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '2020'	System	15 Sep 2020 14:39:22
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User coded data point as SOC: Psychiatric disorders, HLT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\23.0.	(b) (4)	15 Sep 2020 14:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 14:40:50
Data point term sent to Coder	System	15 Sep 2020 14:39:52
User entered 'Attention Deficit Disorder'	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41
	(b) (4)	

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'un Jan 2020'	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Darrell O'Brien (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'Jan 2020'	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '2020'	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered empty.	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered empty.	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '12:21'	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 12:21'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '189.5' cm	(b) (4)	
	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51
	(b) (4)	
DataPoint set to visible.	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '100.9' kg	(b) (4)	
	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51
	(b) (4)	
DataPoint set to visible.	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '28.09783'	System	14 Sep 2020 17:46:51
DataPoint set to visible.	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'kg/m2'	System	14 Sep 2020 17:46:51
DataPoint set to visible.	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'bpm'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'breaths/min'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07

US3342259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:16

US3342259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:16

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '1'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'VISIT1'	System	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '113649'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:08:47
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Answered' (Site from DM).	Olivia Hapanowicz (b) (4)	07 Dec 2020 14:21:39
User entered 'No (N)'	(b) (4) Olivia Hapanowicz (b) (4)	07 Dec 2020 14:21:35
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 22:53:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:10:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:10:52

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '12:21'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 12:21'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '98.0' F	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Oral (Oral)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '103'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'bpm'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '13'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'breaths/min'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '123'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '80'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered missing code ND - Not Done.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Sep 2020 18:46:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Sep 2020 18:46:37
User entered '13:39' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:46:37
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46
	(b) (4)	

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 13:39'	System	14 Sep 2020 18:46:37
User entered empty.	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Sep 2020 18:46:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 18:46:37
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:46:37
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46
	(b) (4)	

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:46:37
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per CDM: Please indicate if pulse is NCS or CS and report AE if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:32:59
Query 'Per CDM: Please indicate if pulse is NCS or CS and report AE if necessary. Thank you' answered with 'entry error, 94' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 18:24:49
User entered '94' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:24:41
User opened query 'Per CDM: Please indicate if pulse is NCS or CS and report AE if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:38:10
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 18:46:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 18:46:37
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:46:37
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'bpm'	System	14 Sep 2020 18:46:37
User entered empty.	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 18:48:40
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	14 Sep 2020 18:48:40
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:48:40
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 18:46:37
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 18:46:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 18:46:37
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:46:37
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'breaths/min'	System	14 Sep 2020 18:46:37
User entered empty.	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Sep 2020 18:48:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 18:48:40
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 18:48:40
User entered empty.	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Sep 2020 18:48:40
Query 'Data is required. Please provide.' answered by System	System	14 Sep 2020 18:48:40
data change (Site from System).		
User entered '79' reason for change: Data Entry	(b) (4), (b) (6)	14 Sep 2020 18:48:40
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:48:46
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'mmHg'	System	14 Sep 2020 18:48:40
User entered empty.	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:48:52

US3342259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:52

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 18:14:38
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 18:14:38
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:48:59
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	Morgan Schulle (b) (4)	14 Sep 2020 17:48:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '13:04' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:14:38
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 13:04'	System	14 Sep 2020 18:14:38
User entered empty.	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:14:38
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'ONCE'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:49:08

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:49:08

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '12:49' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	14 Sep 2020 20:50:32
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 20:50:13
User entered '14:49' reason for change: Data Entry Error	Morgan Schulle (b) (4)	14 Sep 2020 20:50:13
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 17:49:08
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:49:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 12:49'	System	14 Sep 2020 20:50:32
User entered '14 Sep 2020 14:49'	System	14 Sep 2020 20:50:13
User entered empty.	System	14 Sep 2020 17:49:08

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 20:50:24
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 20:50:24
User entered '12:51' reason for change: Data Entry Error	Morgan Schulle (b) (4)	14 Sep 2020 20:50:24
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 17:49:16
User entered empty.	System	14 Sep 2020 17:49:16
	Morgan Schulle (b) (4)	14 Sep 2020 17:49:16
	(b) (4)	

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '14 Sep 2020 12:51'	System	14 Sep 2020 20:50:24
User entered empty.	System	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered empty.	System	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	14 Sep 2020 17:49:21

US3342259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '1'	System	14 Sep 2020 17:49:21

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:43:43', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1e141584-1153-47cb-9db9-839f3e04d938' User entered 'Yes (Y)'	System	14 Sep 2020 18:44:11
	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:43:50', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1e141584-1153-47cb-9db9-839f3e04d938' User entered '97.6'	System	14 Sep 2020 18:44:11
	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:43:57', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1e141584-1153-47cb-9db9-839f3e04d938' User entered 'No (N)'	System	14 Sep 2020 18:44:11
	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:06', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1e141584-1153-47cb-9db9-839f3e04d938' User entered '14 Sep 2020 13:44'	System	14 Sep 2020 18:44:11
	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 13:24'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 15:54'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 16:49'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 2'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:46:19', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '9f5aaa15-e052-4378-a1bf-624b27e238da' User entered 'Yes (Y)'	System	16 Sep 2020 16:48:09
	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:47:51', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '9f5aaa15-e052-4378-a1bf-624b27e238da' User entered '99.6'	System	16 Sep 2020 16:48:09
	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:47:56', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '9f5aaa15-e052-4378-a1bf-624b27e238da' User entered 'No (N)'	System	16 Sep 2020 16:48:09
	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:48:05', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '9f5aaa15-e052-4378-a1bf-624b27e238da' User entered '16 Sep 2020 11:48'	System	16 Sep 2020 16:48:09
	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 3'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 4'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:37:25', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '08b19749-055c-4b04-90dd-87e2a3e0ed10' User entered 'Yes (Y)'	System	17 Sep 2020 17:37:59
	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:37:33', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '08b19749-055c-4b04-90dd-87e2a3e0ed10' User entered '97.4'	System	17 Sep 2020 17:37:59
	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:37:38', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '08b19749-055c-4b04-90dd-87e2a3e0ed10' User entered 'No (N)'	System	17 Sep 2020 17:37:59
	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:37:45', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '08b19749-055c-4b04-90dd-87e2a3e0ed10' User entered '17 Sep 2020 12:37'	System	17 Sep 2020 17:37:59
	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 5'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 6'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 7'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:55', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '319477d8-9341-42dd-b4fa-ba276e35e917' User entered 'Yes (Y)'	System	21 Sep 2020 15:45:30
	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:45:02', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '319477d8-9341-42dd-b4fa-ba276e35e917' User entered '98.2'	System	21 Sep 2020 15:45:30
	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:45:10', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '319477d8-9341-42dd-b4fa-ba276e35e917'	System	21 Sep 2020 15:45:30
User entered 'No (N)'	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:45:29', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '319477d8-9341-42dd-b4fa-ba276e35e917' User entered '21 Sep 2020 10:45'	System	21 Sep 2020 15:45:30
	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:22', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b3b905a7-404e-4870-a65d-d546a897ca81' User entered 'None (1)'	System	14 Sep 2020 18:44:42
	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:25', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b3b905a7-404e-4870-a65d-d546a897ca81' User entered 'No (N)'	System	14 Sep 2020 18:44:42
	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:28', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b3b905a7-404e-4870-a65d-d546a897ca81' User entered 'No (N)'	System	14 Sep 2020 18:44:42
	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:35', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b3b905a7-404e-4870-a65d-d546a897ca81' User entered 'None (1)'	System	14 Sep 2020 18:44:42
	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:41', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b3b905a7-404e-4870-a65d-d546a897ca81' User entered '14 Sep 2020 13:44'	System	14 Sep 2020 18:44:42
	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 13:24'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 15:54'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 16:49'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 2'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:48', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '2042b539-07a5-4e80-8965-c6d5e46f711a' User entered 'None (1)'	System	16 Sep 2020 16:50:34
	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:52', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '2042b539-07a5-4e80-8965-c6d5e46f711a' User entered 'No (N)'	System	16 Sep 2020 16:50:34
	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:59', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '2042b539-07a5-4e80-8965-c6d5e46f711a' User entered 'No (N)'	System	16 Sep 2020 16:50:34
	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:50:03', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '2042b539-07a5-4e80-8965-c6d5e46f711a' User entered 'None (1)'	System	16 Sep 2020 16:50:34
	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:50:29', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '2042b539-07a5-4e80-8965-c6d5e46f711a' User entered '16 Sep 2020 11:50'	System	16 Sep 2020 16:50:34
	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 3'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 4'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:36', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '309f1c44-c2e6-4151-be63-5f05b53b7b20' User entered 'None (1)'	System	17 Sep 2020 17:40:05
	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:40', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '309f1c44-c2e6-4151-be63-5f05b53b7b20' User entered 'No (N)'	System	17 Sep 2020 17:40:05
	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:43', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '309f1c44-c2e6-4151-be63-5f05b53b7b20' User entered 'No (N)'	System	17 Sep 2020 17:40:05
	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:46', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '309f1c44-c2e6-4151-be63-5f05b53b7b20' User entered 'None (1)'	System	17 Sep 2020 17:40:05
	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:50', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '309f1c44-c2e6-4151-be63-5f05b53b7b20' User entered '17 Sep 2020 12:39'	System	17 Sep 2020 17:40:05
	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 5'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 6'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 7'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:43:28', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '134ef0a3-d2b2-47a2-bc66-06822669cec8' User entered 'None (1)'	System	21 Sep 2020 15:43:57
	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:43:33', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '134ef0a3-d2b2-47a2-bc66-06822669cec8' User entered 'No (N)'	System	21 Sep 2020 15:43:57
	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:43:37', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '134ef0a3-d2b2-47a2-bc66-06822669cec8' User entered 'No (N)'	System	21 Sep 2020 15:43:57
	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:43:48', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '134ef0a3-d2b2-47a2-bc66-06822669cec8' User entered 'None (1)'	System	21 Sep 2020 15:43:57
	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:43:54', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '134ef0a3-d2b2-47a2-bc66-06822669cec8' User entered '21 Sep 2020 10:43'	System	21 Sep 2020 15:43:57
	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:51', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:54', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:56', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:44:59', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:45:01', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:45:03', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'None (0)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:45:06', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered 'No (N)'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-14T13:45:11', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '92277c83-8ef8-4ae8-b607-e9c584d10ab9' User entered '14 Sep 2020 13:45'	System	14 Sep 2020 18:46:11
	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 13:24'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 15:54'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '14 Sep 2020 16:49'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 2'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:48:50', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:48:54', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:48:57', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:48:59', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:02', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:04', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'None (0)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:19', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered 'No (N)'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-16T11:49:33', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '1b07cb2c-bd9f-4fd3-bd9d-c34155c69aba' User entered '16 Sep 2020 11:49'	System	16 Sep 2020 16:49:41
	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 3'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 4'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:37:56', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:38:22', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:05', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:08', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:11', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:14', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'None (0)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:21', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered 'No (N)'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-17T12:39:26', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: 'b5b7c9e9-88a6-4794-98e4-13fd6e44df6c' User entered '17 Sep 2020 12:39'	System	17 Sep 2020 17:39:41
	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 5'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 6'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
Data entry locked.	System	14 Sep 2020 18:14:38
User entered 'Day 7'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:06', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:11', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:15', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:20', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:24', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:27', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'None (0)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

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 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:38', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered 'No (N)'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9BD04242-C2CB-46FF-B2B7-19D90377DB03)', Time: '2020-09-21T10:44:43', User OID: 'PatientReportedOutcome (US3342259)', ODM File OID: '477c5825-4417-4741-bf39-a09fad41053d' User entered '21 Sep 2020 10:44'	System	21 Sep 2020 15:44:47
	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:14:38

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:14:38

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '21 Sep 2020'	Ethan Shotton (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Ethan Shotton (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Sep 2020 20:48:43

US3342259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '1'	System	21 Sep 2020 20:48:43

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '29 Sep 2020'	Ethan Shotton (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Ethan Shotton (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Sep 2020 15:30:24

US3342259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '1'	System	29 Sep 2020 15:30:24

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:34:18

US3342259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:07
User entered '1'	System	05 Oct 2020 17:34:18

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered 'VISIT2'	System	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '09:50'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '16 Oct 2020 09:50'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '80'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered 'bpm'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '12'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered 'breaths/min'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '138'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered 'mmHg'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '87'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered 'mmHg'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:21

US3342259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:25:21

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 16:37:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 16:37:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:37:48
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 16:37:44
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:52

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:37:52

US3342259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:38:04

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:42:16
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:25:37
Data point term sent to Coder	System	12 Nov 2020 18:24:23
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'new diagnosis' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:23:37
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:23:32
User entered 'MIGRAINE' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:23:32
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:41
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:17

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	16 Oct 2020 16:45:15
User entered 'Intermittent Migraine'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '20:00'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '14 Sep 2020 20:00'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	16 Oct 2020 16:44:43
User entered '1' reason for change: Data Entry Error	System	16 Oct 2020 16:44:43
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 16:44:28
User entered '0'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Patient reported intermittent migraines starting 14 SEP 2020 at 20:00 and continuing to today 16 OCT 2020. Patient did not seek medical attention and is not on medication.'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '0'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '0'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:42:34
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression suicidal, LLT: Suicidal depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:10:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:10:35
Data point term sent to Coder	System	12 Nov 2020 18:20:19
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' answered with 'updated, should be WITH, not AND' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:19:57
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:19:45
User entered 'DEPRESSION with SUICIDAL IDEATION' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:19:45
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:32
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression suicidal, LLT: Suicidal depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:02
Data point term sent to Coder	System	16 Oct 2020 16:55:41
User entered 'Depression and suicidal ideation'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:55:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User closed query 'Per CDM-Kindly confirm if Ae has ended.If yes then kindly consider to update end .Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:01:09
Query 'Per CDM-Kindly confirm if Ae has ended.If yes then kindly consider to update end .Thank you.' answered with 'pt discontinued from study because this unstable med condition = exclusionary. cannot contact pt about status of this AE because consent withdrawn and AE will remain open.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 12:52:55
User opened query 'Per CDM-Kindly confirm if Ae has ended.If yes then kindly consider to update end .Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:11:32
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 16:55:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 16:55:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:55:35
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 16:55:22
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 16:55:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 16:55:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:55:35
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 16:55:22
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:42:51
Query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:23:00
User opened query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:17:05
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	16 Oct 2020 16:55:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 16:55:35
User entered '0'	System	16 Oct 2020 16:55:22
	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Suicidal ideation - patient went to hospital, saw a doctor but was not admitted and received no medication. Patient let hospital same day. Plans to seek additional help.'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '0'	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '1'	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Acute pharyngitis - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 18:18:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 18:18:34
Data point term sent to Coder	System	12 Nov 2020 18:18:17
User entered 'ACUTE PHARYNGITIS' reason for change: Data Entry Error	Eileen Euperio (b) (4)	12 Nov 2020 18:18:11
Data point term sent to Coder	System	12 Nov 2020 18:17:17
Coding entries removed.	Eileen Euperio (b) (4)	12 Nov 2020 18:16:32
User entered 'AUTO PHARYNGITIS' reason for change: Data Entry Error	Eileen Euperio (b) (4)	12 Nov 2020 18:16:32
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system infections and inflammations, HLT: Encephalitis NEC, PT: Encephalitis autoimmune, LLT: Encephalitis autoimmune - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:53:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:53:55
Data point term sent to Coder	System	16 Oct 2020 16:58:43
User entered 'Auto phrenitis'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '19:00'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '14 Sep 2020 19:00'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '20:00'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '14 Sep 2020 20:00'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Patient reported sore throat following first vaccination on 14 SEP 2020 at 19:00 hours. Patient did not take any medications and symptoms resolved within 24 hours.'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '0'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered '0'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:07:18

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:49:48

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:51:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:51:53
Data point term sent to Coder User entered 'AMBIEN'	System Morgan Schulle (b) (4)	14 Sep 2020 17:51:20 14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'INSOMNIA'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '5'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'mg (mg)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'as needed (PRN)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'UN Jan 2020'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:52:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 17:52:45
Data point term sent to Coder	System	14 Sep 2020 17:52:24
User entered 'VYVANSE'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'ATTENTION DEFICIT DISORDER'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '60'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'mg (mg)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'as needed (PRN)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'UN Jan 2020'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '0'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User entered empty.	System	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:07:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:16
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'No (N)'	Eileen Euperio (b) (4)	17 Nov 2020 16:38:34

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '16 Oct 2020'	Eileen Euperio (b) (4)	12 Nov 2020 18:20:53

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'AE (specify) (ADVERSE EVENT)'	Eileen Euperio (b) (4)	12 Nov 2020 18:20:53

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per CDM Re-query: update is noted; however please record record line number per CCGs (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 15:15:36
Query 'Per CDM Re-query: update is noted; however please record record line number per CCGs (i.e. AE#1 or SAE#1, etc.)' answered with 'Updated' (Site from DM).	Olivia Hapanowicz (b) (4)	19 Jan 2021 15:03:42
User entered 'AE #2' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 15:03:26
User opened query 'Per CDM Re-query: update is noted; however please record record line number per CCGs (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:44:05
Query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs.' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:43:37
User opened query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:13:33
User closed query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:13:33
Query 'Per CDM: per sponsor review, please indicate AE record number.' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4)	19 Nov 2020 23:34:46
User entered 'AE #2, DEPRESSION WITH SUICIDAL IDEATION, PI CHOSE TO WITHDRAW SUBJECT' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 23:34:41
User entered 'AE #2, EPRESSION WITH SUICIDAL IDEATION, PI CHOSE TO WITHDRAW SUBJECT' reason for change: Data Entry Error	Eileen Euperio (b) (4)	19 Nov 2020 23:34:35
User opened query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:44:48
User entered 'depression with suicidal ideation, PI chose to withdraw subject'	Eileen Euperio (b) (4)	12 Nov 2020 18:20:53

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered '16 Oct 2020'	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered 'AE (specify) (ADVERSE EVENT)'	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User closed query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:15:46
Query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs. ' answered with 'Updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Jan 2021 15:04:09
User entered 'AE #2' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	19 Jan 2021 15:04:04
User opened query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:13:55
User closed query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:13:55
Query 'Per CDM: per sponsor review, please indicate AE record number.' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:35:08
User entered 'AE #2 DEPRESSION WITH SUICIDAL IDEATION, PI CHOSE TO WITHDRAW SUBJECT FROM STUDY' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:35:02
User opened query 'Per CDM: per sponsor review, please indicate AE record number.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:44:57
User entered 'depression with suicidal ideation, PI chose to withdraw subject from study'	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:18

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:42
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:32
User entered empty.	Eileen Euperio (b) (4)	12 Nov 2020 18:21:30