

US3342259 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:57:08

All time stamps listed in this document are displayed in GMT

US3342259

Form: Participant Creation

Generated On: 26 Nov 2020 10:57:08

[Participant ID](#)

US3342259

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

US3342259

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

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

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

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

US3342259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3342259

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:08

Were any significant conditions reported?

Yes ☒

No ☐

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

US3342259

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

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.

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

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

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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	

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

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 ☐

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Height	ND - Not Done
Weight	ND - Not Done

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3342259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

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.

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:49 (24 HR)
Collection date and time (derived)	14 SEP 2020 12:49

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:08

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		

US3342259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 10:57:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

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 ☒

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

Yes <input type="checkbox"/>	
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: 26 Nov 2020 10:57:08

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 ☐

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:08

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		16 SEP 2020 12:00
<hr/>		
PC Close Date & Time		17 SEP 2020 11:59
<hr/>		

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

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: 26 Nov 2020 10:57:08

Yes <input type="checkbox"/>	
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: 26 Nov 2020 10:57:08

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 ☐

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:08

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		18 SEP 2020 12:00
<hr/>		
PC Close Date & Time		19 SEP 2020 11:59
<hr/>		

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:08

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 ☐

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:08

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		19 SEP 2020 12:00
<hr/>		
PC Close Date & Time		20 SEP 2020 11:59
<hr/>		

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:08

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 ☒

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:08

Yes <input type="checkbox"/>	
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

Generated On: 26 Nov 2020 10:57:08

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

Generated On: 26 Nov 2020 10:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Generated On: 26 Nov 2020 10:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Generated On: 26 Nov 2020 10:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Generated On: 26 Nov 2020 10:57:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Generated On: 26 Nov 2020 10:57:08

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.

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Generated On: 26 Nov 2020 10:57:08

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

Generated On: 26 Nov 2020 10:57:08

Collection date (*dd MMM yyyy*)

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

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342259

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:08

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

US3342259

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:57:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:08

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)

Generated On: 26 Nov 2020 10:57:08

AEID	
Adverse event	MIGRAINE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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
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)

Generated On: 26 Nov 2020 10:57:08

AEID	
Adverse event	DEPRESSION WITH SUICIDAL IDEATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

Admitted to ICU Derived (CSA Programming Field Only)

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

AEID	
Adverse event	ACUTE PHARYNGITIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input checked="" type="radio"/>
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 <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:08

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)

Generated On: 26 Nov 2020 10:57:08

Name of Medication	AMBIEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INSOMNIA
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		UN JAN 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

Name of Medication	VYVANSE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ATTENTION DEFICIT DISORDER
Dose per administration	60
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		UN JAN 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
<hr/>		
Interval Dosage Unit Number (derived)		<input type="text"/>
<hr/>		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:57:08

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:08

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, DEPRESSION WITH
SUICIDAL IDEATION, PI CHOSE
TO WITHDRAW SUBJECT

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:57:08

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 DEPRESSION WITH
SUICIDAL IDEATION, PI CHOSE
TO WITHDRAW SUBJECT FROM
STUDY

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: 26 Nov 2020 10:57:08

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342259'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Sep 2020 17:14:40

US3342259

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 17:14:41

US3342259

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Sep 2020 17:44:08

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 17:14:42

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Age](#)

Audit	User	Time (GMT)
User entered '41'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '41'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

White

Audit	User	Time (GMT)
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

Unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:08

Not reported

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:22

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:33

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 17:14:41

US3342259

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:08

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:45:38

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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
	(b) (4)	

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	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).	(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: 26 Nov 2020 10:57:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	15 Sep 2020 14:39:22
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:46:17
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:46:17

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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.	Coder Import (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

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'un Jan 2020'	Darrell O'Brien (b) (4) (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 14:39:41

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '12:21'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:21'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '189.5' cm	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51
DataPoint set to visible.	(b) (4) System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '100.9' kg	Morgan Schulle (b) (4)	14 Sep 2020 17:46:51
DataPoint set to visible.	(b) (4) System	14 Sep 2020 17:44:38

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:46:51

US3342259

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:16

US3342259

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:16

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '1'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:46

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Sep 2020 17:47:57

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113649'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Sep 2020 17:39:48

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:06

US3342259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:57:08

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:57:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '12:21'	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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	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: 26 Nov 2020 10:57:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 10:57:08

[If Other, specify](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 10:57:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '103'	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: 26 Nov 2020 10:57:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '13'	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: 26 Nov 2020 10:57:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	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: 26 Nov 2020 10:57:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	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: 26 Nov 2020 10:57:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:57:08

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:57:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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 '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) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Temperature (xxx.x)

Audit	User	Time (GMT)
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 '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) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:46:37
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: 26 Nov 2020 10:57:08

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	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 '79' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	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) (b) (4)	14 Sep 2020 17:48:46

US3342259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:52

US3342259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:52

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
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).	System	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) (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

If No, reason not given

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '13:04' reason for change: Data Entry Error	(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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:14:38
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:48:59
	(b) (4)	

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 17:48:59

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:08

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:08

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:49' reason for change: Data Entry Error	Morgan Schulle (b) (4)	14 Sep 2020 20:50:32
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
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

US3342259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	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: 26 Nov 2020 10:57:08

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:57:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	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).	System	14 Sep 2020 17:49:16
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:57:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:49:16

US3342259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:21

US3342259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:49:21

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:11
User entered 'Yes (Y)'	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:11
User entered '97.6'	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:11
User entered 'No (N)'	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:11
User entered '14 Sep 2020 13:44'	System	14 Sep 2020 18:44:11

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:48:09
User entered 'Yes (Y)'	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:48:09
User entered 'No (N)'	System	16 Sep 2020 16:48:09

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:37:59
User entered 'Yes (Y)'	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:37:59
User entered '97.4'	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:37:59
User entered 'No (N)'	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:37:59
User entered '17 Sep 2020 12:37'	System	17 Sep 2020 17:37:59

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:45:30
User entered 'Yes (Y)'	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:45:30
User entered '98.2'	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:45:30
User entered '21 Sep 2020 10:45'	System	21 Sep 2020 15:45:30

US3342259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:42
User entered 'None (1)'	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:42
User entered 'No (N)'	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:42
User entered 'No (N)'	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:42
User entered 'None (1)'	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:44:42
User entered '14 Sep 2020 13:44'	System	14 Sep 2020 18:44:42

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:50:34
User entered 'None (1)'	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:50:34
User entered 'No (N)'	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:50:34
User entered 'No (N)'	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:50:34
User entered '16 Sep 2020 11:50'	System	16 Sep 2020 16:50:34

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:40:05
User entered 'None (1)'	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:40:05
User entered 'No (N)'	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:40:05
User entered 'No (N)'	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:40:05
User entered 'None (1)'	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:40:05
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 17:40:05

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:43:57
User entered 'No (N)'	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:43:57
User entered 'No (N)'	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:08

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:43:57
User entered 'None (1)'	System	21 Sep 2020 15:43:57

US3342259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

HEADACHE

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

FATIGUE

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

CHILLS

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'None (0)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered 'No (N)'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:46:11
User entered '14 Sep 2020 13:45'	System	14 Sep 2020 18:46:11

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

HEADACHE

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

FATIGUE

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

CHILLS

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'None (0)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered 'No (N)'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 16:49:41
User entered '16 Sep 2020 11:49'	System	16 Sep 2020 16:49:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

CHILLS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'None (0)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered 'No (N)'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 17:39:41
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 17:39:41

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:44:47
User entered 'None (0)'	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 15:44:47
User entered 'No (N)'	System	21 Sep 2020 15:44:47

US3342259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:08

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 20:48:39

US3342259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 20:48:43

US3342259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 20:48:43

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	29 Sep 2020 15:30:19

US3342259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	29 Sep 2020 15:30:24

US3342259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 15:30:24

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:34:13

US3342259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:34:18

US3342259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 17:34:18

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Oct 2020 16:21:01

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '09:50'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 16:23:59

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:25:11

US3342259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:25:21

US3342259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:25:21

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

[If No, reason not given](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:33:14

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:37:25

US3342259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 10:57:08

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:57:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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: 26 Nov 2020 10:57:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:37:44

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:37:52

US3342259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:37:52

US3342259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:38:04

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Adverse event](#)

Audit	User	Time (GMT)
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) (6)	13 Nov 2020 18:42:16
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (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)	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)	12 Nov 2020 18:23:37
Coding entries removed.	Eileen Euperio (b) (4)	12 Nov 2020 18:23:32
User entered 'MIGRAINE' reason for change: Data Entry Error	Eileen Euperio (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, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (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)	17 Oct 2020 09:54:17
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

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '20:00'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 20:00'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 16:44:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	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).	System	16 Oct 2020 16:44:28
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Narrative](#)

Audit	User	Time (GMT)
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) (6)	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 16:44:28

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Adverse event](#)

Audit	User	Time (GMT)
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) (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)	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)	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)	12 Nov 2020 18:19:57
Coding entries removed.	Eileen Euperio (b) (4)	12 Nov 2020 18:19:45
User entered 'DEPRESSION with SUICIDAL IDEATION' reason for change: Data Entry Error	Eileen Euperio (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)	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)	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

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:57:08

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 16:55:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	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).	System	16 Oct 2020 16:55:22
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Narrative](#)

Audit	User	Time (GMT)
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) (6)	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 16:55:22

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (b) (4)	12 Nov 2020 18:16:32
User entered 'AUTO PHARYNGITIS' reason for change: Data Entry Error	Eileen Euperio (b) (4) (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) (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) (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) (b) (4)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '19:00'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 19:00'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '20:00'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 20:00'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Narrative](#)

Audit	User	Time (GMT)
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) (6)	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 16:58:30

US3342259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 16:58:30

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:49:48

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Name of Medication](#)

Audit	User	Time (GMT)
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	System	14 Sep 2020 17:51:20
User entered 'AMBIEN'	Morgan Schulle (b) (4)	14 Sep 2020 17:50:38
	(b) (4)	

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'INSOMNIA'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:50:38

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'ATTENTION DEFICIT DISORDER'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:57:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:51:28

US3342259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:57:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	17 Nov 2020 16:38:34

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:08

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:20:53

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:08

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:20:53

US3342259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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	Eileen Euperio (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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	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: 26 Nov 2020 10:57:08

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	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: 26 Nov 2020 10:57:08

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

Audit	User	Time (GMT)
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)	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)	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)	12 Nov 2020 18:21:30

US3342259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:57:08

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:57:08

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:57:08

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:57:08

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	12 Nov 2020 18:21:30