

US3342239 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:03

All time stamps listed in this document are displayed in GMT

US3342239

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:03

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:03

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	02 MAR 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	02 MAR 2012
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2012
Start Year (derived)	2012
Stop Month and Year (derived)	MAR 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN MAR 2019
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)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

Condition	L5 DEFECTIVE DISC
Start date (dd MMM yyyy)	UN MAR 2019
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)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:48 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:48
Height (<i>xxx.x</i>)	162.5 cm
Weight (<i>xxx.x</i>)	64.2 kg
BMI (<i>xxx.x</i>)	24.31243 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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	02 MAR 2012
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 113263

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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)	10 SEP 2020
Time of assessment (00:00-23:59)	16:48 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:48
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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)	10 SEP 2020
Time of assessment (00:00-23:59)	18:17 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 18:17
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 SEP 2020
What was the treatment time? (00:00-23:59)	17:46 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 17:46
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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	17:18 (24 HR)
Collection date and time (derived)	10 SEP 2020 17:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:03

Collection date (<i>dd MMM yyyy</i>)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:20	10 SEP 2020 17:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

10 SEP 2020 18:22

PC Open Date & Time

10 SEP 2020 18:06

PC Close Date & Time

10 SEP 2020 20:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	11 SEP 2020 03:53
PC Open Date & Time	10 SEP 2020 21:31
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	12 SEP 2020 04:24
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	13 SEP 2020 05:22
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 02:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:03

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 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

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

97.2 °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

15 SEP 2020 16:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

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

99.2 °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

16 SEP 2020 23:23

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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

10 SEP 2020 18:24

PC Open Date & Time

10 SEP 2020 18:06

PC Close Date & Time

10 SEP 2020 20:36

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 03:59

PC Open Date & Time

10 SEP 2020 21:31

PC Close Date & Time

11 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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 ☐

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

30

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)**

40

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

12 SEP 2020 04:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

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 ☒

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

13 SEP 2020 05:24

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

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

14 SEP 2020 02:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:03

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

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

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 ☒

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

15 SEP 2020 16:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

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

16 SEP 2020 23:24

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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 ☐

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 18:25
PC Open Date & Time	10 SEP 2020 18:06
PC Close Date & Time	10 SEP 2020 20:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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 ☐

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 04:01
PC Open Date & Time	10 SEP 2020 21:31
PC Close Date & Time	11 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 05:25
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 02:12
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:03

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 ☐

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:03

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		14 SEP 2020 12:00
<hr/>		
PC Close Date & Time		15 SEP 2020 11:59
<hr/>		

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:53
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 23:24
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 17 SEP 2020 23:22

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 23:22
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

Was Contact Attempted?

Yes ☒

No ☐

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

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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)	13 OCT 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:27
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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	

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

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.

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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 SUBJECT HAD AE OF HEAD
TRAUMA FOLLOWING
PHLEBOTOMY ATTEMPT.
BLOOD AND NP SWABS NOT
COLLECTED, IP NOT
ADMINISTERED

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? _____

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Was the sample collected?

Yes ☐

No ☒

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:03

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		

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3X ATTEMPTED CALLS
UNSUCCESSFUL

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 16:27:44
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3342239

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:03

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

AEID	
Adverse event	HEAD TRAUMA
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)	13 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 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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:03

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

Yes ☒

No ☐

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

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

Name of Medication	BUSPIRONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
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 checked="" 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 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"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN JUN 2018
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2019
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	300
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 checked="" 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 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"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN JUN 2018
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN FEB 2019	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="radio"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

Name of Medication	BUSPAR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	30
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 checked="" 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 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"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

	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 (<i>dd MMM yyyy</i>)	UN JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		UN JUN 2018
<hr/>		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

Name of Medication	NAPROXEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INJECTION SITE PAIN
Dose per administration	220
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"/>

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342239

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:03

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3342239

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:03

Date of dosing discontinuation (dd MMM yyyy)

13 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 1

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

Date of study discontinuation/completion (*dd MMM yyyy*) 11 NOV 2020

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3342239 (Prod: Tekton Research- Austin)

US3342239

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:03

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342239'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 22:04:27

US3342239

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:29:34

US3342239

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 22:04:28

US3342239

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:29:34

US3342239

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Sep 2020 22:29:34

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 22:04:29

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Age](#)

Audit	User	Time (GMT)
User entered '30'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '30'	System	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

White

Audit	User	Time (GMT)
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

Unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:03

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:10

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:34

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 22:04:28

US3342239

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:03

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:22

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:52:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:52:43
Data point term sent to Coder	System	10 Sep 2020 22:51:28
User entered 'bilateral tubal ligation'	Andrew Bell (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '02 Mar 2012'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '02 Mar 2012'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Mar 2012'	System	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2012'	System	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Mar 2012'	System	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2012'	System	10 Sep 2020 22:50:57

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:52:44
Data point term sent to Coder	System	10 Sep 2020 22:51:28
User entered 'gallstones'	Andrew Bell (b) (4)	10 Sep 2020 22:51:16
	(b) (4)	

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Mar 2019'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:45:55
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:24:56
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Mar 2019'	System	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2019'	System	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:16

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Disc lesion lumbar - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:54:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:54:39
Data point term sent to Coder	System	10 Sep 2020 22:52:32
User entered 'L5 defective disc'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Mar 2019'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Mar 2019'	System	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2019'	System	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:37

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:53:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:53:44
Data point term sent to Coder	System	10 Sep 2020 22:52:29
User entered 'anxiety'	Andrew Bell (b) (4)	10 Sep 2020 22:51:55
	(b) (4)	

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Jan 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2018'	System	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:51:55

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:46:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:25:55
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:53:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 22:53:44
Data point term sent to Coder	System	10 Sep 2020 22:52:32
User entered 'hypertension'	Andrew Bell (b) (4)	10 Sep 2020 22:52:12
	(b) (4)	

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Jun 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Jun 2018'	System	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2018'	System	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:52:12

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '16:48'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:48'	System	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '162.5' cm	Morgan Schulle (b) (4)	10 Sep 2020 22:36:28
DataPoint set to visible.	(b) (4) System	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '64.2' kg	Morgan Schulle (b) (4)	10 Sep 2020 22:36:28
DataPoint set to visible.	(b) (4) System	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '24.31243'	System	10 Sep 2020 22:36:28
DataPoint set to visible.	System	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	10 Sep 2020 22:36:28
DataPoint set to visible.	System	10 Sep 2020 22:30:41

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 22:36:28

US3342239

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:03

US3342239

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:03

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '02 Mar 2012'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:03

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:37:48

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

[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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '1'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:03

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:38:17

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:39:53

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:39:53

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:39:53

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Sep 2020 22:39:53

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 22:19:21

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113263'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 22:19:21

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

[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) [REDACTED]	10 Sep 2020 22:19:21

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:40:06

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:40:06

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:40:06

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:40:06

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:40:06

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:05:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:05:56

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '16:48'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:48'	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '16'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:03

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 23:21:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 23:21:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:41:21
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '18:17' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:17'	System	10 Sep 2020 23:21:33
User entered empty.	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 23:21:33
User entered empty.	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 23:21:33
User entered empty.	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 23:21:33
User entered empty.	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 20:13:33
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Deemed clinically insignificant by investigator' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 14:27:38
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:32:56
User entered '54' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:21:33
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 23:21:33
User entered empty.	System	10 Sep 2020 22:41:21

US3342239

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:26

US3342239

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:26

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

[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	10 Sep 2020 23:01:18
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	10 Sep 2020 23:01:18
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	10 Sep 2020 22:41:35
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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)	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '17:46' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:01:18
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:46'	System	10 Sep 2020 23:01:18
User entered empty.	System	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

[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)	10 Sep 2020 23:01:18
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:35
	(b) (4)	

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 22:41:35

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:43

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:43

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 23:13:03
User entered '17:18' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 23:13:03
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:41:43
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:43

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:18'	System	10 Sep 2020 23:13:03
User entered empty.	System	10 Sep 2020 22:41:43

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

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	10 Sep 2020 23:13:13
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Sep 2020 23:13:13
User entered '17:20' reason for change: Data Entry Error	Andrew Bell (b) (4)	10 Sep 2020 23:13:13
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:41:51
User entered empty.	Morgan Schulle (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:20'	System	10 Sep 2020 23:13:13
User entered empty.	System	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:41:51

US3342239

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	10 Sep 2020 22:41:57

US3342239

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 22:41:57

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a'	System	10 Sep 2020 23:22:59
User entered 'Yes (Y)'	System	10 Sep 2020 23:22:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a'	System	10 Sep 2020 23:22:59
User entered '98.9'	System	10 Sep 2020 23:22:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:46', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a'	System	10 Sep 2020 23:22:59
User entered 'No (N)'	System	10 Sep 2020 23:22:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:55', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a'	System	10 Sep 2020 23:22:59
User entered '10 Sep 2020 18:22'	System	10 Sep 2020 23:22:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:36'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d'	System	11 Sep 2020 08:53:18
User entered 'Yes (Y)'	System	11 Sep 2020 08:53:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d'	System	11 Sep 2020 08:53:18
User entered '98.4'	System	11 Sep 2020 08:53:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d'	System	11 Sep 2020 08:53:18
User entered 'No (N)'	System	11 Sep 2020 08:53:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:53:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d'	System	11 Sep 2020 08:53:18
User entered '11 Sep 2020 03:53'	System	11 Sep 2020 08:53:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 21:31'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 2'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:36', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered 'Yes (Y)'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered '98.9'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered 'Yes (Y)'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:23:38
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	Darrell O'Brien (b) (4)	02 Oct 2020 19:40:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Sep 2020 09:24:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered '1'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:23:40
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	Darrell O'Brien (b) (4)	02 Oct 2020 19:40:34
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Sep 2020 09:24:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered '1'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'	System	12 Sep 2020 09:24:41
User entered '12 Sep 2020 04:24'	System	12 Sep 2020 09:24:41

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 3'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:44', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered 'Yes (Y)'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:50', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered '98.5'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered 'Yes (Y)'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:23:44
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	Darrell O'Brien (b) (4)	02 Oct 2020 19:41:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 10:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered '1'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:23:47
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	Darrell O'Brien (b) (4)	02 Oct 2020 19:41:16
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 10:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered '1'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:08', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'	System	13 Sep 2020 10:22:10
User entered '13 Sep 2020 05:22'	System	13 Sep 2020 10:22:10

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 4'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c'	System	14 Sep 2020 07:12:17
User entered 'Yes (Y)'	System	14 Sep 2020 07:12:17

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:06', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c'	System	14 Sep 2020 07:12:17
User entered '98.1'	System	14 Sep 2020 07:12:17

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:10', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c'	System	14 Sep 2020 07:12:17
User entered 'No (N)'	System	14 Sep 2020 07:12:17

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c'	System	14 Sep 2020 07:12:17
User entered '14 Sep 2020 02:12'	System	14 Sep 2020 07:12:17

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 5'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 6'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:28', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563'	System	15 Sep 2020 21:53:12
User entered 'Yes (Y)'	System	15 Sep 2020 21:53:12

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563'	System	15 Sep 2020 21:53:12
User entered '97.2'	System	15 Sep 2020 21:53:12

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563'	System	15 Sep 2020 21:53:12
User entered 'No (N)'	System	15 Sep 2020 21:53:12

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563'	System	15 Sep 2020 21:53:12
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:53:12

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 7'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12'	System	17 Sep 2020 04:27:34
User entered 'Yes (Y)'	System	17 Sep 2020 04:27:34

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:23', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12'	System	17 Sep 2020 04:27:34
User entered '99.2'	System	17 Sep 2020 04:27:34

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12'	System	17 Sep 2020 04:27:34
User entered 'No (N)'	System	17 Sep 2020 04:27:34

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12'	System	17 Sep 2020 04:27:34
User entered '16 Sep 2020 23:23'	System	17 Sep 2020 04:27:34

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-10T18:23:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a'	System	10 Sep 2020 23:24:28
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 23:24:28

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a'	System	10 Sep 2020 23:24:28
User entered 'No (N)'	System	10 Sep 2020 23:24:28

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a'	System	10 Sep 2020 23:24:28
User entered 'No (N)'	System	10 Sep 2020 23:24:28

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-10T18:24:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a'	System	10 Sep 2020 23:24:28
User entered 'None (1)'	System	10 Sep 2020 23:24:28

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a'	System	10 Sep 2020 23:24:28
User entered '10 Sep 2020 18:24'	System	10 Sep 2020 23:24:28

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:36'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-11T03:54:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:55:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered 'No (N)'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:55:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered 'Yes (Y)'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:58:19', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered '30'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-11T03:59:23', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:59:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef'	System	11 Sep 2020 08:59:54
User entered '11 Sep 2020 03:59'	System	11 Sep 2020 08:59:54

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 21:31'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 2'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-12T04:25:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:28:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered 'Yes (Y)'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered '30'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered 'Yes (Y)'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered '40'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-12T04:30:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:30:35', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8'	System	12 Sep 2020 09:30:40
User entered '12 Sep 2020 04:30'	System	12 Sep 2020 09:30:40

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 3'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-13T05:22:21', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da'	System	13 Sep 2020 10:24:47
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	13 Sep 2020 10:24:47

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da'	System	13 Sep 2020 10:24:47
User entered 'No (N)'	System	13 Sep 2020 10:24:47

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:23:58', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da'	System	13 Sep 2020 10:24:47
User entered 'No (N)'	System	13 Sep 2020 10:24:47

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-13T05:24:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da'	System	13 Sep 2020 10:24:47
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 10:24:47

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da'	System	13 Sep 2020 10:24:47
User entered '13 Sep 2020 05:24'	System	13 Sep 2020 10:24:47

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 4'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-14T02:12:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d'	System	14 Sep 2020 07:12:37
User entered 'None (1)'	System	14 Sep 2020 07:12:37

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:22', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d'	System	14 Sep 2020 07:12:37
User entered 'No (N)'	System	14 Sep 2020 07:12:37

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d'	System	14 Sep 2020 07:12:37
User entered 'No (N)'	System	14 Sep 2020 07:12:37

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-14T02:12:29', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d'	System	14 Sep 2020 07:12:37
User entered 'None (1)'	System	14 Sep 2020 07:12:37

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d'	System	14 Sep 2020 07:12:37
User entered '14 Sep 2020 02:12'	System	14 Sep 2020 07:12:37

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 5'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 6'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-15T16:53:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2'	System	15 Sep 2020 21:53:33
User entered 'None (1)'	System	15 Sep 2020 21:53:33

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2'	System	15 Sep 2020 21:53:33
User entered 'No (N)'	System	15 Sep 2020 21:53:33

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:17', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2'	System	15 Sep 2020 21:53:33
User entered 'No (N)'	System	15 Sep 2020 21:53:33

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-15T16:53:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2'	System	15 Sep 2020 21:53:33
User entered 'None (1)'	System	15 Sep 2020 21:53:33

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2'	System	15 Sep 2020 21:53:33
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:53:33

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 7'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-16T23:23:57', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4'	System	17 Sep 2020 04:27:38
User entered 'None (1)'	System	17 Sep 2020 04:27:38

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4'	System	17 Sep 2020 04:27:38
User entered 'No (N)'	System	17 Sep 2020 04:27:38

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4'	System	17 Sep 2020 04:27:38
User entered 'No (N)'	System	17 Sep 2020 04:27:38

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-16T23:24:03', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4'	System	17 Sep 2020 04:27:38
User entered 'None (1)'	System	17 Sep 2020 04:27:38

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:07', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4'	System	17 Sep 2020 04:27:38
User entered '16 Sep 2020 23:24'	System	17 Sep 2020 04:27:38

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:33', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'None (0)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'None (0)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'None (0)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'None (0)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'None (0)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-10T18:25:11', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered 'No (N)'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:25:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7'	System	10 Sep 2020 23:25:18
User entered '10 Sep 2020 18:25'	System	10 Sep 2020 23:25:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:36'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:59:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'None (0)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:32', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'No interference with activity (1)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'None (0)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'None (0)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'None (0)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'None (0)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-11T04:00:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered 'No (N)'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:01:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7'	System	11 Sep 2020 09:01:09
User entered '11 Sep 2020 04:01'	System	11 Sep 2020 09:01:09

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 21:31'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 2'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:30:53', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'None (0)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'No interference with activity (1)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:08', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'None (0)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:11', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'None (0)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:31', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'None (0)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-12T04:31:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered 'No (N)'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:53', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8'	System	12 Sep 2020 09:31:58
User entered '12 Sep 2020 04:31'	System	12 Sep 2020 09:31:58

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 3'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:57', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:25:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'None (0)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-13T05:25:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered 'No (N)'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:25:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3'	System	13 Sep 2020 10:25:17
User entered '13 Sep 2020 05:25'	System	13 Sep 2020 10:25:17

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 4'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:40', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'None (0)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-14T02:12:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered 'No (N)'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630'	System	14 Sep 2020 07:13:04
User entered '14 Sep 2020 02:12'	System	14 Sep 2020 07:13:04

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 5'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 6'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:32', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'None (0)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'No interference with activity (1)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:41', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'None (0)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'None (0)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:46', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'None (0)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'None (0)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-15T16:53:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered 'No (N)'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:55', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401'	System	15 Sep 2020 21:54:03
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 7'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'None (0)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'No interference with activity (1)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'None (0)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'None (0)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:41', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'None (0)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'None (0)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-16T23:24:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered 'No (N)'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982'	System	17 Sep 2020 04:27:36
User entered '16 Sep 2020 23:24'	System	17 Sep 2020 04:27:36

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:54:03
User entered 'Day 8'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:21:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '956cb39d-9d48-4019-a15a-a54bd0c9ff8d'	System	18 Sep 2020 04:22:06
User entered 'None (0)'	System	18 Sep 2020 04:22:06

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '956cb39d-9d48-4019-a15a-a54bd0c9ff8d'	System	18 Sep 2020 04:22:06
User entered '17 Sep 2020 23:22'	System	18 Sep 2020 04:22:06

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:54:03
User entered 'Day 8'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

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 (d0db8a44b142a52b)', Time: '2020-09-17T23:22:09', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'c5ddea70-a3e6-416a-acb1-a0e7a01af8fa'	System	18 Sep 2020 04:22:16
User entered 'No (N)'	System	18 Sep 2020 04:22:16

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:22:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'c5ddea70-a3e6-416a-acb1-a0e7a01af8fa' User entered '17 Sep 2020 23:22'	System	18 Sep 2020 04:22:16

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:54:03

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:54:03

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 21:35:45

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 21:35:45

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[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)	18 Sep 2020 21:35:45

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 21:35:45

US3342239

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 21:35:50

US3342239

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 21:35:50

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	24 Sep 2020 16:07:17

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	24 Sep 2020 16:07:17

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[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)	24 Sep 2020 16:07:17

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	24 Sep 2020 16:07:17

US3342239

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	24 Sep 2020 16:07:21

US3342239

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 16:07:21

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 18:39:41

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 18:39:41

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[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)	01 Oct 2020 18:39:41

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 18:39:41

US3342239

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 18:39:45

US3342239

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 18:39:45

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:01:29

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:01:29

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 20:01:29

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 20:01:29

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '14:27'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:27'	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Pulse (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '102'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 16:44:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 16:44:20
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:44:20
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:02:21
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:02:21

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:02:26

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:02:26

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

If No, reason not given

Audit	User	Time (GMT)
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'subject had AE of head trauma following phlebotomy attempt. Blood and NP swabs not collected, IP not administered'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:45:52

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:57

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:57

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:45:57

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:45:57

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:46:02

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:02:29

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 20:02:29

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:26:52

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:26:52

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:26:52

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '3X attempted calls unsuccessful'	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:26:52

US3342239

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:26:59

US3342239

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:26:59

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered 'Day 64'	System	10 Sep 2020 23:01:18

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:30', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5'	System	13 Nov 2020 22:27:47
User entered 'No (N)'	System	13 Nov 2020 22:27:47

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5'	System	13 Nov 2020 22:27:47
User entered 'No (N)'	System	13 Nov 2020 22:27:47

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:44', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5'	System	13 Nov 2020 22:27:47
User entered '13 Nov 2020 16:27:44'	System	13 Nov 2020 22:27:47

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 23:01:18

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:01:18
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 23:01:18

US3342239

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:10

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:47:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:47:31
Data point term sent to Coder	System	14 Oct 2020 16:47:02
User entered 'head trauma'	Eileen Euperio (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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)	20 Nov 2020 12:37:33
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 dosing disc. CRF' (Site from DM).	Eileen Euperio (b) (4)	19 Nov 2020 23:25:07
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 23:24:39
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 23:24:39
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:59:51
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 16:15:53
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Eileen Euperio (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 16:46:41

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 16:46:41

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:52:39

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
Data point term sent to Coder	System	10 Sep 2020 22:54:35
User entered 'buspirone'	Andrew Bell (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Jun 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Feb 2019'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 22:53:38

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
Data point term sent to Coder	System	10 Sep 2020 22:54:35
User entered 'Gabapentin'	Andrew Bell (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Jun 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Feb 2019'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 22:54:28

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 22:55:46
Data point term sent to Coder	System	10 Sep 2020 22:55:35
User entered 'buspar'	Andrew Bell (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'UN Jan 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jun 2018'	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:55:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 22:55:18
User entered 'No (N)' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:18
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:55:10
User entered empty.	Andrew Bell (b) (4) (b) (4)	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 22:55:10

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:43:49
Data point term sent to Coder	System	02 Oct 2020 19:42:56
User entered 'Naproxen'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Indication](#)

Audit	User	Time (GMT)
User entered 'Injection Site Pain'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '220'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:42:26

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:42:26

US3342239

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:03

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	19 Nov 2020 23:24:39
User entered '11 Nov 2020'	Eileen Euperio (b) (4)	11 Nov 2020 22:59:51

US3342239

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:03

[Primary reason for dosing discontinuation](#)

Audit	User		Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Eileen Euperio	(b) (4)	19 Nov 2020 23:24:39
reason for change: Data Entry Error	(b) (4)		
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Eileen Euperio	(b) (4)	11 Nov 2020 22:59:51
	(b) (4)		

US3342239

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered 'AE 1' reason for change: Data Entry Error	Eileen Euperio (b) (4)	19 Nov 2020 23:24:39
User entered empty.	Eileen Euperio (b) (4)	11 Nov 2020 22:59:51

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:45:18
Query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	19 Nov 2020 23:27:11
User opened query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 18:59:18
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Eileen Euperio (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:03

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	11 Nov 2020 23:00:12