

US3622012 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:08:38

All time stamps listed in this document are displayed in GMT

US3622012

Form: Participant Creation

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

[Participant ID](#)

US3622012

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

US3622012

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	23
Age Units	YEARS
Age (Derived)	23
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3622012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3622012

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Condition	OCCASIONAL HEADACHES
Start date (dd MMM yyyy)	01 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:00
Height (<i>xxx.x</i>)	63.8 in
Weight (<i>xxx.x</i>)	98.3 lb
BMI (<i>xxx.x</i>)	17.01461 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was the pregnancy test performed?	Yes ☒
	No ☐

Date of test (dd MMM yyyy)	11 AUG 2020

Test performed	Urine ☒
	Serum ☐

Result	Positive ☐
	Negative ☒

Was FSH sample collected?	Yes ☐
	No ☒

Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Aug 2020 02:16:25

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Aug 2020 02:16:25

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 102640

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:00
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	117 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	16:19 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:19
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	121 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Sep 2020 12:34:24

Generated On: 26 Nov 2020 11:08:38

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 AUG 2020

What was the treatment time? (00:00-23:59) 15:44 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 15:44

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

11 AUG 2020 13:30

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:35	11 AUG 2020 13:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Aug 2020 02:16:25

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 AUG 2020 16:12

PC Open Date & Time

11 AUG 2020 16:04

PC Close Date & Time

11 AUG 2020 18:34

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp 11 AUG 2020 19:51

PC Open Date & Time 11 AUG 2020 19:29

PC Close Date & Time 12 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

12 AUG 2020 12:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

13 AUG 2020 19:32

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:35

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:31

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

17 AUG 2020 19:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:13

PC Open Date & Time

11 AUG 2020 16:04

PC Close Date & Time

11 AUG 2020 18:34

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:52

PC Open Date & Time

11 AUG 2020 19:29

PC Close Date & Time

12 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

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 AUG 2020 19:32

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

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 AUG 2020 19:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

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 ☒

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 AUG 2020 19:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

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

16 AUG 2020 19:32

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

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

17 AUG 2020 19:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:13
PC Open Date & Time	11 AUG 2020 16:04
PC Close Date & Time	11 AUG 2020 18:34

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 19:53
PC Open Date & Time	11 AUG 2020 19:29
PC Close Date & Time	12 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	12 AUG 2020 12:05
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	13 AUG 2020 19:33
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	14 AUG 2020 19:32
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	15 AUG 2020 19:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	16 AUG 2020 19:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

Yes ☐	
PC Time stamp	17 AUG 2020 19:37
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3622012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3622012

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622012

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622012

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	06:40 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 06:40
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	118 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

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

US3622012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

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.

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (dd MMM yyyy)	10 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

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?

US3622012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

07:15 (24 HR)

Collection date and time (derived)

10 SEP 2020 07:15

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:20	10 SEP 2020 07:20
Nasopharyngeal Swab 2	No		

US3622012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622012

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622012

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:08:38

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

US3622012

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:08:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622012

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Sep 2020 16:04:54

Generated On: 26 Nov 2020 11:08:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	29 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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) _____	

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Aug 2020 02:16:24

Generated On: 26 Nov 2020 11:08:38

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

Yes ☒

No ☐

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

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Name of Medication ACETOMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

Name of Medication	XANAX
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	UNKNOWN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Nov 2020 16:11:35

Generated On: 26 Nov 2020 11:08:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:38

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3622012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:38

Date of dosing discontinuation (dd MMM yyyy)

4 SEP 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 LOG LINE 1

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

Date of study discontinuation/completion (dd MMM yyyy) 13 NOV 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☒
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify PARTICIPANT MOVED OUT OF STATE.

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

Audit

US3622012 (Prod: University of Miami)

US3622012

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'US3622012'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:41

US3622012

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:12:52

US3622012

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:42

US3622012

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 19:12:52

US3622012

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 19:12:52

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered (b) (6) 1996'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:04:43

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Age](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '23'	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '23'	System	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

Sex

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Female (F)'	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Ethnicity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Black](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '1'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

Unknown

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:38

[Not reported](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:10:14

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 19:13:08

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	RWS_ENDPOINT	11 Aug 2020 19:04:42
	ENDPOINT (b) (4)	

US3622012

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	05 Nov 2020 15:15:34
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	05 Nov 2020 15:15:34
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:10:32

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:49:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:49:00
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	10 Nov 2020 16:11:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:17:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:17:19
Data point term sent to Coder	System	05 Nov 2020 15:16:48
User entered 'occasional headaches'	Junlin Long (b) (4) (b) (4)	05 Nov 2020 15:16:25

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
User entered '01 Aug 2020'	Junlin Long (b) (4)	05 Nov 2020 15:16:25
	(b) (4)	

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Nov 2020 15:16:25
	(b) (4)	

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Nov 2020 15:16:25
	(b) (4)	

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Nov 2020 15:16:25
	(b) (4)	

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Nov 2020 15:16:25
	(b) (4)	

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	05 Nov 2020 15:16:25

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Nov 2020 15:16:25

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:16:25

US3622012

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:16:25

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '13:00'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:00'	System	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '63.8' in	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:11:47
DataPoint set to visible.	System	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '98.3' lb	(b) (4), (b) (6)	12 Aug 2020 16:11:47
DataPoint set to visible.	System	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '17.01461'	System	16 Sep 2020 23:52:18
User closed query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:31:30
Query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' answered with 'Values confirmed.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:26:15
User opened query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:16:19
User entered '17.0'	System	12 Aug 2020 16:11:47
DataPoint set to visible.	System	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Aug 2020 16:11:47
DataPoint set to visible.	System	11 Aug 2020 19:13:19

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered '98.8' F	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered '117'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered '18'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered '123'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:11
User entered '87'	(b) (4), (b) (6)	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:11:47

US3622012

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:12:10

US3622012

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 17:56:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 12:15:10
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:12:10

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:12:33

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4)	12 Aug 2020 16:13:06
	(b) (4), (b) (6)	

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:13:06

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4)	12 Aug 2020 16:13:52
	(b) (4), (b) (6)	

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:38

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:13:52

US3622012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:13:35

US3622012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:13:35

US3622012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 19:13:35

US3622012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 19:13:35

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:47

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:40:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:40:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 19:04:47
User entered '102640' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:47

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:47

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 19:14:23

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:14:23

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4)	11 Aug 2020 19:14:23
	(b) (4), (b) (6)	

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 19:14:23

US3622012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:38

[Liver Disease](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 19:14:23

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

Height

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '63.8' in	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '98.3' lb	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '63.8' in	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '98.3' lb	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) [REDACTED]	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '13:00'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:00'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '98.8' F	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '117'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '123'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '87'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

Height

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '63.8' in	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:38

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:42
User entered '98.3' lb	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 16:05:41
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 16:16:19
User entered '16:19'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:19'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '98.2' F	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '121'	(b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '17'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '121'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered '100'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:16:19

US3622012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:16:34

US3622012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 15:05:28
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:16:34

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User closed query ' Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 10:44:37
Query ' Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you. ' answered with 'changed to no; this was not on the eCRF completion guidelines' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:49:54
Signature has been broken.	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User opened query ' Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:08:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:34:24
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark response for Was FSH sample collected? as No. Thank you' (Site from DM). Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark response for Was FSH sample collected? as No. Thank you' answered with 'FSH marked no' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 04:20:14
Signature has been broken.	(b) (4), (b) (6)	16 Sep 2020 16:11:30
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Sep 2020 16:11:12
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark response for Was FSH sample collected? as No. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 11:34:07
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:49:50
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:49:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:17:12

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '15:44'	(b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:44'	System	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:53:38

US3622012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:17:31

US3622012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:17:31

US3622012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '13:30'	(b) (4), (b) (6)	12 Aug 2020 16:17:31

US3622012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:30'	System	12 Aug 2020 16:17:31

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '13:35'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:35'	System	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:17:50

US3622012

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:17:58

US3622012

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:17:58

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2ff432eb-2cbf-4a1d-863b-25f8cbf28d7e'	System	11 Aug 2020 20:12:38
User entered 'Yes (Y)'	System	11 Aug 2020 20:12:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:19', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2ff432eb-2cbf-4a1d-863b-25f8cbf28d7e'	System	11 Aug 2020 20:12:38
User entered '98.2'	System	11 Aug 2020 20:12:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:25', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2ff432eb-2cbf-4a1d-863b-25f8cbf28d7e'	System	11 Aug 2020 20:12:38
User entered 'No (N)'	System	11 Aug 2020 20:12:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:34', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2ff432eb-2cbf-4a1d-863b-25f8cbf28d7e'	System	11 Aug 2020 20:12:38
User entered '11 Aug 2020 16:12'	System	11 Aug 2020 20:12:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:04'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:34'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:50:53', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd7666417-d0b7-46b5-8107-f0812fc5dc0f'	System	11 Aug 2020 23:51:26
User entered 'Yes (Y)'	System	11 Aug 2020 23:51:26

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:51:01', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd7666417-d0b7-46b5-8107-f0812fc5dc0f'	System	11 Aug 2020 23:51:26
User entered '98.8'	System	11 Aug 2020 23:51:26

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:51:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd7666417-d0b7-46b5-8107-f0812fc5dc0f'	System	11 Aug 2020 23:51:26
User entered 'No (N)'	System	11 Aug 2020 23:51:26

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:51:22', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd7666417-d0b7-46b5-8107-f0812fc5dc0f'	System	11 Aug 2020 23:51:26
User entered '11 Aug 2020 19:51'	System	11 Aug 2020 23:51:26

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:29'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 2'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:03:56', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '8317e724-4aec-4b6f-8c02-e8009378cfd5'	System	12 Aug 2020 16:04:17
User entered 'Yes (Y)'	System	12 Aug 2020 16:04:17

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '8317e724-4aec-4b6f-8c02-e8009378cfd5'	System	12 Aug 2020 16:04:17
User entered '98.4'	System	12 Aug 2020 16:04:17

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '8317e724-4aec-4b6f-8c02-e8009378cfd5'	System	12 Aug 2020 16:04:17
User entered 'No (N)'	System	12 Aug 2020 16:04:17

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:15', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '8317e724-4aec-4b6f-8c02-e8009378cfd5'	System	12 Aug 2020 16:04:17
User entered '12 Aug 2020 12:04'	System	12 Aug 2020 16:04:17

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 3'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:31:46', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'dc6b2e2f-078b-4ba6-802c-4bb9fdffccf2'	System	13 Aug 2020 23:32:06
User entered 'Yes (Y)'	System	13 Aug 2020 23:32:06

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:31:53', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'dc6b2e2f-078b-4ba6-802c-4bb9fdffccf2'	System	13 Aug 2020 23:32:06
User entered '98.4'	System	13 Aug 2020 23:32:06

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:31:56', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'dc6b2e2f-078b-4ba6-802c-4bb9fdffccf2'	System	13 Aug 2020 23:32:06
User entered 'No (N)'	System	13 Aug 2020 23:32:06

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:04', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'dc6b2e2f-078b-4ba6-802c-4bb9fdffccf2'	System	13 Aug 2020 23:32:06
User entered '13 Aug 2020 19:32'	System	13 Aug 2020 23:32:06

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 4'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:05', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '0e2585b6-dd2d-4d3c-954f-5b13fe0a573e'	System	14 Aug 2020 23:31:29
User entered 'Yes (Y)'	System	14 Aug 2020 23:31:29

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:11', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '0e2585b6-dd2d-4d3c-954f-5b13fe0a573e' User entered '98.5'	System	14 Aug 2020 23:31:29

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:16', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '0e2585b6-dd2d-4d3c-954f-5b13fe0a573e'	System	14 Aug 2020 23:31:29
User entered 'No (N)'	System	14 Aug 2020 23:31:29

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:26', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '0e2585b6-dd2d-4d3c-954f-5b13fe0a573e' User entered '14 Aug 2020 19:31'	System	14 Aug 2020 23:31:29
	System	14 Aug 2020 23:31:29

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 5'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:34:44', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '65466bac-0727-41f8-9ae8-55c6a52633f2'	System	15 Aug 2020 23:35:05
User entered 'Yes (Y)'	System	15 Aug 2020 23:35:05

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:34:48', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '65466bac-0727-41f8-9ae8-55c6a52633f2'	System	15 Aug 2020 23:35:05
User entered '98.4'	System	15 Aug 2020 23:35:05

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:34:54', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '65466bac-0727-41f8-9ae8-55c6a52633f2'	System	15 Aug 2020 23:35:05
User entered 'No (N)'	System	15 Aug 2020 23:35:05

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:35:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '65466bac-0727-41f8-9ae8-55c6a52633f2'	System	15 Aug 2020 23:35:05
User entered '15 Aug 2020 19:35'	System	15 Aug 2020 23:35:05

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 6'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:34', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'fbc21cd3-7f0b-4045-961e-4c620a57c11f'	System	16 Aug 2020 23:31:52
User entered 'Yes (Y)'	System	16 Aug 2020 23:31:52

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:39', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'fbc21cd3-7f0b-4045-961e-4c620a57c11f' User entered '98.5'	System	16 Aug 2020 23:31:52

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:42', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'fbc21cd3-7f0b-4045-961e-4c620a57c11f'	System	16 Aug 2020 23:31:52
User entered 'No (N)'	System	16 Aug 2020 23:31:52

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:51', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'fbc21cd3-7f0b-4045-961e-4c620a57c11f' User entered '16 Aug 2020 19:31'	System	16 Aug 2020 23:31:52
	System	16 Aug 2020 23:31:52

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 7'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:20', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '69e2910b-db52-4415-aad6-293e49e6906a'	System	17 Aug 2020 23:36:37
User entered 'Yes (Y)'	System	17 Aug 2020 23:36:37

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:25', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '69e2910b-db52-4415-aad6-293e49e6906a'	System	17 Aug 2020 23:36:37
User entered '98.4'	System	17 Aug 2020 23:36:37

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:27', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '69e2910b-db52-4415-aad6-293e49e6906a'	System	17 Aug 2020 23:36:37
User entered 'No (N)'	System	17 Aug 2020 23:36:37

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:31', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '69e2910b-db52-4415-aad6-293e49e6906a'	System	17 Aug 2020 23:36:37
User entered '17 Aug 2020 19:36'	System	17 Aug 2020 23:36:37

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:54', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd40ed3bb-8c05-4575-8fc2-7a2d11338fe8'	System	11 Aug 2020 20:13:19
User entered 'None (1)'	System	11 Aug 2020 20:13:19

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:12:58', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd40ed3bb-8c05-4575-8fc2-7a2d11338fe8'	System	11 Aug 2020 20:13:19
User entered 'No (N)'	System	11 Aug 2020 20:13:19

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:01', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd40ed3bb-8c05-4575-8fc2-7a2d11338fe8'	System	11 Aug 2020 20:13:19
User entered 'No (N)'	System	11 Aug 2020 20:13:19

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:08', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd40ed3bb-8c05-4575-8fc2-7a2d11338fe8'	System	11 Aug 2020 20:13:19
User entered 'None (1)'	System	11 Aug 2020 20:13:19

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:13', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'd40ed3bb-8c05-4575-8fc2-7a2d11338fe8' User entered '11 Aug 2020 16:13'	System	11 Aug 2020 20:13:19
	System	11 Aug 2020 20:13:19

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:04'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:34'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:51:45', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'e8b3864e-7d3b-4135-afed-d268f63f8b11'	System	11 Aug 2020 23:52:39
User entered 'None (1)'	System	11 Aug 2020 23:52:39

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:51:58', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'e8b3864e-7d3b-4135-afed-d268f63f8b11'	System	11 Aug 2020 23:52:39
User entered 'No (N)'	System	11 Aug 2020 23:52:39

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:52:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'e8b3864e-7d3b-4135-afed-d268f63f8b11'	System	11 Aug 2020 23:52:39
User entered 'No (N)'	System	11 Aug 2020 23:52:39

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:52:21', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'e8b3864e-7d3b-4135-afed-d268f63f8b11'	System	11 Aug 2020 23:52:39
User entered 'None (1)'	System	11 Aug 2020 23:52:39

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:52:37', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'e8b3864e-7d3b-4135-afed-d268f63f8b11'	System	11 Aug 2020 23:52:39
User entered '11 Aug 2020 19:52'	System	11 Aug 2020 23:52:39

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:29'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 2'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:22', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5affd5e5-0b9e-4995-8bea-fd33986d47c2'	System	12 Aug 2020 16:04:59
User entered 'None (1)'	System	12 Aug 2020 16:04:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:30', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5affd5e5-0b9e-4995-8bea-fd33986d47c2'	System	12 Aug 2020 16:04:59
User entered 'No (N)'	System	12 Aug 2020 16:04:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:40', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5affd5e5-0b9e-4995-8bea-fd33986d47c2'	System	12 Aug 2020 16:04:59
User entered 'No (N)'	System	12 Aug 2020 16:04:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:49', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5affd5e5-0b9e-4995-8bea-fd33986d47c2'	System	12 Aug 2020 16:04:59
User entered 'None (1)'	System	12 Aug 2020 16:04:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:04:55', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5affd5e5-0b9e-4995-8bea-fd33986d47c2'	System	12 Aug 2020 16:04:59
User entered '12 Aug 2020 12:04'	System	12 Aug 2020 16:04:59

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 3'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:23', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '14d6af06-0cbb-44ad-a403-6333b8754f47'	System	13 Aug 2020 23:32:45
User entered 'None (1)'	System	13 Aug 2020 23:32:45

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:29', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '14d6af06-0cbb-44ad-a403-6333b8754f47'	System	13 Aug 2020 23:32:45
User entered 'No (N)'	System	13 Aug 2020 23:32:45

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:33', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '14d6af06-0cbb-44ad-a403-6333b8754f47'	System	13 Aug 2020 23:32:45
User entered 'No (N)'	System	13 Aug 2020 23:32:45

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:40', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '14d6af06-0cbb-44ad-a403-6333b8754f47'	System	13 Aug 2020 23:32:45
User entered 'None (1)'	System	13 Aug 2020 23:32:45

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:43', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '14d6af06-0cbb-44ad-a403-6333b8754f47'	System	13 Aug 2020 23:32:45
User entered '13 Aug 2020 19:32'	System	13 Aug 2020 23:32:45

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 4'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:32', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'a1e0e7b1-179a-43d8-8ed5-f643fe27b4a9'	System	14 Aug 2020 23:31:49
User entered 'None (1)'	System	14 Aug 2020 23:31:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:35', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'a1e0e7b1-179a-43d8-8ed5-f643fe27b4a9'	System	14 Aug 2020 23:31:49
User entered 'No (N)'	System	14 Aug 2020 23:31:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:37', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'a1e0e7b1-179a-43d8-8ed5-f643fe27b4a9'	System	14 Aug 2020 23:31:49
User entered 'No (N)'	System	14 Aug 2020 23:31:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:40', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'a1e0e7b1-179a-43d8-8ed5-f643fe27b4a9'	System	14 Aug 2020 23:31:49
User entered 'None (1)'	System	14 Aug 2020 23:31:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:45', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'a1e0e7b1-179a-43d8-8ed5-f643fe27b4a9'	System	14 Aug 2020 23:31:49
User entered '14 Aug 2020 19:31'	System	14 Aug 2020 23:31:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 5'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:31:53', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ef12e7c-b53e-4493-bee4-2aff863d359f'	System	15 Aug 2020 23:32:38
User entered 'None (1)'	System	15 Aug 2020 23:32:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:04', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ef12e7c-b53e-4493-bee4-2aff863d359f'	System	15 Aug 2020 23:32:38
User entered 'No (N)'	System	15 Aug 2020 23:32:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:17', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ef12e7c-b53e-4493-bee4-2aff863d359f'	System	15 Aug 2020 23:32:38
User entered 'No (N)'	System	15 Aug 2020 23:32:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:28', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ef12e7c-b53e-4493-bee4-2aff863d359f'	System	15 Aug 2020 23:32:38
User entered 'None (1)'	System	15 Aug 2020 23:32:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:35', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ef12e7c-b53e-4493-bee4-2aff863d359f'	System	15 Aug 2020 23:32:38
User entered '15 Aug 2020 19:32'	System	15 Aug 2020 23:32:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 6'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:54', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2a1368af-47fa-4085-b047-0b83b02b98f7'	System	16 Aug 2020 23:32:09
User entered 'None (1)'	System	16 Aug 2020 23:32:09

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:57', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2a1368af-47fa-4085-b047-0b83b02b98f7'	System	16 Aug 2020 23:32:09
User entered 'No (N)'	System	16 Aug 2020 23:32:09

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:31:59', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2a1368af-47fa-4085-b047-0b83b02b98f7'	System	16 Aug 2020 23:32:09
User entered 'No (N)'	System	16 Aug 2020 23:32:09

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2a1368af-47fa-4085-b047-0b83b02b98f7'	System	16 Aug 2020 23:32:09
User entered 'None (1)'	System	16 Aug 2020 23:32:09

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:05', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2a1368af-47fa-4085-b047-0b83b02b98f7'	System	16 Aug 2020 23:32:09
User entered '16 Aug 2020 19:32'	System	16 Aug 2020 23:32:09

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 7'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:35', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2edae842-701f-494e-b465-edf01585d76d'	System	17 Aug 2020 23:36:49
User entered 'None (1)'	System	17 Aug 2020 23:36:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:37', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2edae842-701f-494e-b465-edf01585d76d'	System	17 Aug 2020 23:36:49
User entered 'No (N)'	System	17 Aug 2020 23:36:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:40', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2edae842-701f-494e-b465-edf01585d76d'	System	17 Aug 2020 23:36:49
User entered 'No (N)'	System	17 Aug 2020 23:36:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:43', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2edae842-701f-494e-b465-edf01585d76d'	System	17 Aug 2020 23:36:49
User entered 'None (1)'	System	17 Aug 2020 23:36:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:47', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2edae842-701f-494e-b465-edf01585d76d'	System	17 Aug 2020 23:36:49
User entered '17 Aug 2020 19:36'	System	17 Aug 2020 23:36:49

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:20', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409'	System	11 Aug 2020 20:13:45
User entered 'None (0)'	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:22', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409' User entered 'None (0)'	System	11 Aug 2020 20:13:45
	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:25', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409'	System	11 Aug 2020 20:13:45
User entered 'None (0)'	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:28', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409' User entered 'None (0)'	System	11 Aug 2020 20:13:45
	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:30', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409'	System	11 Aug 2020 20:13:45
User entered 'None (0)'	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:32', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409' User entered 'None (0)'	System	11 Aug 2020 20:13:45
	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:38', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409'	System	11 Aug 2020 20:13:45
User entered 'No (N)'	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T16:13:44', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '5484b8e6-0853-4e36-9502-ca5fcb695409' User entered '11 Aug 2020 16:13'	System	11 Aug 2020 20:13:45
	System	11 Aug 2020 20:13:45

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:04'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:34'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:06', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:11', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:18', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:20', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'None (0)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:28', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered 'No (N)'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-11T19:53:37', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '910db93f-ab16-4852-a34b-290e1ffbe222'	System	11 Aug 2020 23:53:38
User entered '11 Aug 2020 19:53'	System	11 Aug 2020 23:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:29'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 2'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:00', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:05', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:08', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:11', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:14', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:17', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'None (0)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:21', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered 'No (N)'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-12T12:05:26', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '76aa824a-7ad9-4542-b1ed-e8579bc5d1d7'	System	12 Aug 2020 16:05:30
User entered '12 Aug 2020 12:05'	System	12 Aug 2020 16:05:30

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 3'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:53', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:56', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:32:58', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:33:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:33:04', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:33:06', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'None (0)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:33:11', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered 'No (N)'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-13T19:33:16', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '6ee3fdbbc-3a38-4a89-a1a6-b01197a46ec9'	System	13 Aug 2020 23:33:20
User entered '13 Aug 2020 19:33'	System	13 Aug 2020 23:33:20

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 4'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:49', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:52', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:54', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:57', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:31:59', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:32:02', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'None (0)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:32:07', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered 'No (N)'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-14T19:32:12', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '75741a09-c6c1-4e24-9949-9215b547a431'	System	14 Aug 2020 23:32:14
User entered '14 Aug 2020 19:32'	System	14 Aug 2020 23:32:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 5'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:40', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:46', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:49', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:51', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:32:58', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:33:00', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'None (0)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:33:06', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered 'No (N)'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-15T19:33:10', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '2d6a7a73-4af4-4848-ae0f-55a890aa2246'	System	15 Aug 2020 23:33:14
User entered '15 Aug 2020 19:33'	System	15 Aug 2020 23:33:14

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 6'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:09', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:11', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:13', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:15', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:18', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:19', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'None (0)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:21', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered 'No (N)'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-16T19:32:27', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: '212f143f-abb3-4af7-91ce-e9ec72ef136c'	System	16 Aug 2020 23:32:31
User entered '16 Aug 2020 19:32'	System	16 Aug 2020 23:32:31

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:53:38
User entered 'Day 7'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:51', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:55', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:36:57', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:37:00', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:37:01', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:37:03', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'None (0)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

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 (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:37:05', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered 'No (N)'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7788329-E373-46CF-9984-51B520222CE4)', Time: '2020-08-17T19:37:10', User OID: 'PatientReportedOutcome (US3622012)', ODM File OID: 'b916ab16-3e1c-4945-9a2f-3b6a69fa8144'	System	17 Aug 2020 23:37:12
User entered '17 Aug 2020 19:37'	System	17 Aug 2020 23:37:12

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:53:38

US3622012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:53:38

US3622012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:38:34

US3622012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:38:34

US3622012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:38:34

US3622012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:38:34

US3622012

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:38:21

US3622012

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:38:21

US3622012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:05:41

US3622012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '28 Aug 2020'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 13:05:41

US3622012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:05:41

US3622012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:05:41

US3622012

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 13:05:56

US3622012

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 13:05:56

US3622012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 12:14:48

US3622012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered '4 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 12:14:48

US3622012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:14:48

US3622012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:14:48

US3622012

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 12:14:57

US3622012

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 12:14:57

US3622012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 12:15:10

US3622012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '10 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:15:10

US3622012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 12:15:10

US3622012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 12:15:10

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered '06:40'	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 06:40'	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '118'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '24'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '140'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '95'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	10 Sep 2020 12:17:06
	(b) (4), (b) (6)	

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:06

US3622012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:13

US3622012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 12:17:13

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:24:41

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:17:59

US3622012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:18:16

US3622012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:16

US3622012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '07:15'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:16

US3622012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 07:15'	System	10 Sep 2020 12:18:16

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '07:20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 07:20'	System	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 12:18:29

US3622012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 12:18:34

US3622012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 12:18:34

US3622012

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 12:54:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:57:32

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
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)	04 Sep 2020 20:00:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:00:46
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 19:59:43
User entered 'anxiety'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '29 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Ongoing?](#)

Audit	User	Time (GMT)
Signature has been broken.	Junlin Long (b) (4) (b) (4)	19 Nov 2020 13:58:34
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	19 Nov 2020 13:58:34
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 11:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM; provide end date when available' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:12:45
Query 'Per CDM; provide end date when available' answered with 'end date entered' (Site from DM).	Junlin Long (b) (4)	19 Nov 2020 13:58:46
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	19 Nov 2020 13:58:34
	(b) (4)	
User entered '4 Sep 2020' reason for change: New Information	Junlin Long (b) (4)	19 Nov 2020 13:58:34
	(b) (4)	
User opened query 'Per CDM; provide end date when available' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 15:51:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User closed query 'Per MM: Please review and confirm the seriousness of the event as the severity is Grade 3. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:43:02
Query 'Per MM: Please review and confirm the seriousness of the event as the severity is Grade 3. ' answered with 'Per PI does not meet criteria for a serious event' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:52:52
User opened query 'Per MM: Please review and confirm the seriousness of the event as the severity is Grade 3. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:24:38
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:28:51
Comment added 'Event judged not related by investigator. Participant requested to withdraw from receiving second dose of IP.'	(b) (4), (b) (6)	10 Sep 2020 12:19:35
Comment added 'Event judged not related by investigator. Participant requested to withdraw from receiving second dose of IP.'	(b) (4), (b) (6)	04 Sep 2020 20:02:03
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	04 Sep 2020 19:58:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:43:36
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'IP Discontinuation form completed' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:58:08
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:36:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Outcome](#)

Audit	User	Time (GMT)
Signature has been broken.	Junlin Long (b) (4)	19 Nov 2020 13:58:34
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Junlin Long (b) (4)	19 Nov 2020 13:58:34
New Information	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 19:58:46

US3622012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:58:46

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:18:19

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:02:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:02:27
Data point term sent to Coder	System	05 Nov 2020 15:20:55
Coding entries removed.	Junlin Long (b) (4) (b) (4)	05 Nov 2020 15:20:13
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	22 Aug 2020 02:16:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:29:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:29:10
Data point term sent to Coder	System	12 Aug 2020 16:19:24
User entered 'acetaminophen'	(b) (4), (b) (6) (b) (4)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 12:41:45
Signature has been broken.	Junlin Long (b) (4)	05 Nov 2020 15:20:13
User entered 'occasional HEADACHE' reason for change: New Information	(b) (4) Junlin Long (b) (4)	05 Nov 2020 15:20:13
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'mh updated' (Site from DM).	(b) (4) Junlin Long (b) (4)	05 Nov 2020 15:16:47
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:10:12
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'headache'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '1000'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '01 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:14

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:22:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:22:19
Data point term sent to Coder	System	05 Nov 2020 15:20:55
Coding entries removed.	Junlin Long (b) (4) (b) (4)	05 Nov 2020 15:20:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	22 Aug 2020 02:16:25
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:21:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:21:10
Data point term sent to Coder	System	12 Aug 2020 16:20:24
User entered 'ibuprofen'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:11:35
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	05 Nov 2020 15:20:28
	(b) (4)	
User entered 'occasional HEADACHE' reason for change: New Information	Junlin Long (b) (4)	05 Nov 2020 15:20:28
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'headache'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '200'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '01 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 02:16:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:19:53

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:08:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:08:51
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 20:07:59
User entered 'hydroxyzine'	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered '25'	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:07:35

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:09:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:09:51
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 20:09:01
User entered 'xanax'	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered '29 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:08:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:08:43
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:26
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:04:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:08:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:08:43
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:26
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:08:26

US3622012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:08:26

US3622012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:38

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete 'End of Study / Study Discontinuation' form. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 18:02:50
User closed query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 18:02:27
Query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' answered with 'date confirmed' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 19:23:53
Query 'Per CDM: Please complete 'End of Study / Study Discontinuation' form. Thank you' answered with 'ppt. continues on study as per protocol' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 19:23:44
User opened query 'Per CDM: Please confirm the 'Date of dosing discontinuation' or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:25:43
User opened query 'Per CDM: Please complete 'End of Study / Study Discontinuation' form. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:09:23
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:15
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:10

US3622012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:15
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:57:10

US3622012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Requery: Kindly remove the "please refer" and consider to update only the AE log line#. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:46:25
Query 'Per CDM: Requery: Kindly remove the "please refer" and consider to update only the AE log line#. Thank you.' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	20 Nov 2020 13:12:51
User entered 'AE log line 1' reason for change: Per Query Resolution	(b) (4)	20 Nov 2020 13:12:36
User opened query 'Per CDM: Requery: Kindly remove the "please refer" and consider to update only the AE log line#. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:05:59
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:03:36
Query 'Per CDM: Please record AE record number instead of details ' answered with 'ae record number entered' (Site from DM).	Junlin Long (b) (4)	19 Nov 2020 15:34:22
Signature has been broken.	Junlin Long (b) (4)	19 Nov 2020 15:33:57
User entered 'please refer to ae line 1.' reason for change: Per Query Resolution	Junlin Long (b) (4)	19 Nov 2020 15:33:57
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:28:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:47:15
User entered 'Ppt. decided to withdraw from the study secondary to anxiety. Per PI anxiety was unrelated to IP.'	(b) (4), (b) (6)	28 Sep 2020 17:57:10

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review and reconcile the date of study discontinuation /completion date with dosing discontinuation date and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 04:25:24
Query 'Per CDM: Please review and reconcile the date of study discontinuation /completion date with dosing discontinuation date and update accordingly or else clarify. Thank you.' answered with 'date confirmed according to PI's notes' (Site from DM).	Junlin Long (b) (4)	18 Nov 2020 15:39:32
User opened query 'Per CDM: Please review and reconcile the date of study discontinuation /completion date with dosing discontinuation date and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:16:09
User entered '13 Nov 2020'	Junlin Long (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

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

Audit	User	Time (GMT)
User entered 'participant moved out of state.'	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56

US3622012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:38

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Nov 2020 15:17:56