

US3322199 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:00:04

All time stamps listed in this document are displayed in GMT

US3322199

Form: Participant Creation

Generated On: 26 Nov 2020 11:00:04

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

Generated On: 26 Nov 2020 11:00:04

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:00:04

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:04

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

Condition	BONE SPUR SURGERY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

Condition	ARRHYTHMIA (SUPRAVENTRICULAR TACHYCARDIA)
Start date (dd MMM yyyy)	UN JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

Condition	BACK SURGERY
Start date (dd MMM yyyy)	31 OCT 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2017
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

Condition	ECZEMA
Start date (dd MMM yyyy)	UN SEP 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

Condition	LEFT BUNDLE BRANCH BLOCK
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

Condition	PRE-DIABETES
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

Condition	BONE SPUR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

Condition	HYPERCHOLESTEREMIA
Start date (dd MMM yyyy)	UN JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:00
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	225 lb
BMI (<i>xxx.x</i>)	31.44675 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

NETWORK ADMINISTRATOR (IT FIELD)
IN A SCHOOL.

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

Generated On: 26 Nov 2020 11:00:04

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)	False
Other	True
Specify	<ul style="list-style-type: none">- INTERACTS WITH 5+ PEOPLE ON A WORK DAY- GOES TO WORK 5/WEEK- PLACE OF WORSHIP 1+/WEEK- STORES 2+/WEEK- ATTENDS GATHERINGS OF 10 + PEOPLE 2 OR MORE TIMES A MONTH

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 111240

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	17:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 17:17
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	2 SEP 2020
What was the treatment time? (00:00-23:59)	16:42 (24 HR)
Treatment Date and Time (derived)	2 SEP 2020 16:42
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	2 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:18 (24 HR)
Collection date and time (derived)	2 SEP 2020 16:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:04

Collection date (<i>dd MMM yyyy</i>)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	2 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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 11:00:04

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

02 SEP 2020 17:21

PC Open Date & Time

02 SEP 2020 17:02

PC Close Date & Time

02 SEP 2020 19:32

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

02 SEP 2020 22:13

PC Open Date & Time

02 SEP 2020 20:27

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:38

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

98.2 °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

07 SEP 2020 19:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:31

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 17:22

PC Open Date & Time

02 SEP 2020 17:02

PC Close Date & Time

02 SEP 2020 19:32

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

02 SEP 2020 22:13

PC Open Date & Time

02 SEP 2020 20:27

PC Close Date & Time

03 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

03 SEP 2020 23:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

04 SEP 2020 18:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

05 SEP 2020 22:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

06 SEP 2020 18:38

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

07 SEP 2020 19:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

08 SEP 2020 18:31

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 ☐

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 17:22
PC Open Date & Time	02 SEP 2020 17:02
PC Close Date & Time	02 SEP 2020 19:32

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 ☐

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 22:14
PC Open Date & Time	02 SEP 2020 20:27
PC Close Date & Time	03 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:19
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:39
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3322199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:24
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3322199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	1 OCT 2020
What was the treatment time? (00:00-23:59)	11:52 (24 HR)
Treatment Date and Time (derived)	1 OCT 2020 11:52
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3322199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	1 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:40 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:40

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

01 OCT 2020 12:28

PC Open Date & Time

01 OCT 2020 12:12

PC Close Date & Time

01 OCT 2020 14:42

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 98.1 °F

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

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

PC Time Stamp	01 OCT 2020 19:02
PC Open Date & Time	01 OCT 2020 15:37
PC Close Date & Time	02 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 19:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

98.2 °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

03 OCT 2020 19:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 20:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

98.4 °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

06 OCT 2020 19:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 19:48

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

01 OCT 2020 12:28

PC Open Date & Time

01 OCT 2020 12:12

PC Close Date & Time

01 OCT 2020 14:42

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

01 OCT 2020 19:03

PC Open Date & Time

01 OCT 2020 15:37

PC Close Date & Time

02 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

02 OCT 2020 19:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

03 OCT 2020 19:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

04 OCT 2020 20:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

05 OCT 2020 19:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

06 OCT 2020 19:02

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

07 OCT 2020 19:49

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 ☐

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 12:29
PC Open Date & Time	01 OCT 2020 12:12
PC Close Date & Time	01 OCT 2020 14:42

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 ☐

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 19:04
PC Open Date & Time	01 OCT 2020 15:37
PC Close Date & Time	02 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:44
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:33
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 19:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 ☒

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 19:49
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3322199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

MULTIPLE UNSUCCESSFUL
ATTEMPTS, PATIENT FINALLY
RESPONDED ON 13-OCT-2020,
OUT OF WINDOW

US3322199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:19
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	47 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3322199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:45 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:45

US3322199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 15:48:50
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3322199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322199

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:00:04

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:04

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

AEID	USA-US060-2020-MRNA-1273-P30 1000012
Adverse event	FATAL MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

132 of 1111

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input checked="" type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

SAE TERM: MYOCARDIAL
INFARCTION
OUTCOME: FATAL
CAUSALITY: NOT IP RELATED
VACCINATION #1: 02-SEP-2020
VACCINATION #2: 01-OCT-2020
C3: 30-OCT-2020

SUBJECT'S SISTER CALLED OUR
SITE TO INFORM THAT
SUBJECT PASSED AWAY ON
16-NOV-2020 FROM A MASSIVE
HEART ATTACK. SUBJECT HAD
MULTIPLE CARDIAC RISK
FACTORS INCLUDING
HYPERTENSION (2018),
PRE-DIABETES (2019),
SUPRAVENTRICULAR
TACHYCARDIA (2019),
OBESITY, HYPERLIPIDEMIA
(2019), LEFT BUNDLE BRANCH
BLOCK (1976). FURTHER
DETAILS NOT AVAILABLE.
MEDICAL RECORDS BEING
REQUESTED
THERE IS INSUFFICIENT
INFORMATION TO DETERMINE
IF THERE WERE ANY NEW
CONCOMITANT MEDICATIONS,
NON-STUDY VACCINATIONS,
PROHIBITED MEDICATIONS, OR
COVID SYMPTOMS. DOES NOT
APPEAR TO BE COVID-19
RELATED SINCE SUBJECT'S
SISTER REPORTED A MAJOR
HEART ATTACK. MEDICAL
RECORDS PENDING.

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

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:00:04

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

Yes ☒

No ☐

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

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

Name of Medication	ATENOLOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ARYTHMIA/HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

Name of Medication	AMLODIPINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CARDIAC PROPHYLAXIS
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTREMIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

US3322199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:00:04

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3322199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:04

Date of dosing discontinuation (dd MMM yyyy)

16 NOV 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 _____

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

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

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 16 NOV 2020

Was autopsy performed?

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

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

SAEID	USA-US060-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:04

SAEID	USA-US060-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	23/NOV/2020 18:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322199 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322199

Form: Participant Creation

Generated On: 26 Nov 2020 11:00:04

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322199'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:54:15

US3322199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:35

US3322199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:54:16

US3322199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:35

US3322199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Sep 2020 14:42:35

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:54:17

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Age](#)

Audit	User	Time (GMT)
User entered '64'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '64'	System	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[White](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Black](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:04

Not reported

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:54:16

US3322199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:33

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:44:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:44:46
Data point term sent to Coder	System	03 Sep 2020 14:44:07
User entered 'Hypertension'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN Sep 2018'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Sep 2018'	System	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2018'	System	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:43:56

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:37:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'ASSOCIATED CONDITION, BONE SPUR, ADDED TO MED HISTORY ECRF' (Site from DM).	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:40:51
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:56:43
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone lesion excision, LLT: Bone spur removal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:49
Data point term sent to Coder	System	03 Sep 2020 14:45:07
User entered 'Bone Spur Surgery'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Sep 2020 14:44:37

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:08:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:08:45
Data point term sent to Coder	System	03 Sep 2020 14:48:16
User entered 'Arrhythmia (Supraventricular tachycardia)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN Jan 2019'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2019'	System	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:47:58

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:48:51
Data point term sent to Coder	System	03 Sep 2020 14:48:17
User entered 'Penicillin Allergy'	Frances Saubon (b) (4)	03 Sep 2020 14:48:13
	(b) (4)	

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1959'	System	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:48:13

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:49:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:49:42
Data point term sent to Coder	System	03 Sep 2020 14:49:18
User entered 'Back Surgery'	Frances Saubon (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '31 Oct 2017'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '31 Oct 2017'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Oct 2017'	System	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2017'	System	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Oct 2017'	System	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2017'	System	03 Sep 2020 14:48:42

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:49:43
Data point term sent to Coder	System	03 Sep 2020 14:49:19
User entered 'Eczema'	Frances Saubon (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN Sep 2016'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Sep 2016'	System	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:49:06

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block left, LLT: Left bundle branch block - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:50:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:50:49
Data point term sent to Coder	System	03 Sep 2020 14:50:20
User entered 'Left Bundle Branch Block'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN UNK 1976'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1976'	System	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:49:44

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:03:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:03:52
Data point term sent to Coder	System	15 Oct 2020 15:00:11
User entered 'Pre-Diabetes'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN Feb 2019'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Feb 2019'	System	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2019'	System	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:59:25

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Bone spur - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 20:49:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 20:49:32
Data point term sent to Coder	System	15 Oct 2020 20:40:54
User entered 'BONE SPUR'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered 'I'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2012'	System	15 Oct 2020 20:39:59

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesteremia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 21:17:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 21:17:28
Data point term sent to Coder	System	19 Oct 2020 21:16:21
User entered 'hypercholesteremia'	Elisa Moralez (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2019'	System	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:16:05

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '15:00'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:00'	System	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '71' in	Frances Saubon (b) (4)	03 Sep 2020 14:52:24
DataPoint set to visible.	(b) (4) System	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '225' lb	Frances Saubon (b) (4)	03 Sep 2020 14:52:24
DataPoint set to visible.	(b) (4) System	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '31.44675'	System	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 14:52:24

US3322199

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:32

US3322199

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:32

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

[Specify](#)

Audit	User	Time (GMT)
User entered 'Network Administrator (IT Field) in a school.'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:04

[Specify](#)

Audit	User	Time (GMT)
User entered '- interacts with 5+ people on a work day - goes to work 5/week - place of worship 1+/week - stores 2+/week - attends gatherings of 10 + people 2 or more times a month'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:01:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:01:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	03 Sep 2020 15:01:40
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:59:56
User entered empty.	Frances Saubon (b) (4)	03 Sep 2020 14:59:56

US3322199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	03 Sep 2020 15:01:40
User entered empty.	Frances Saubon (b) (4)	03 Sep 2020 14:59:56

US3322199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)' reason for change:	Frances Saubon (b) (4)	03 Sep 2020 15:01:40
Data Entry Error	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	03 Sep 2020 14:59:56
	(b) (4)	

US3322199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Sep 2020 15:01:40
User entered empty.	System	03 Sep 2020 14:59:56

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Sep 2020 20:59:31

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '111240'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Sep 2020 20:59:31

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:59:31

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 20:14:36
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:02:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:02:03

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '15:00'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 15:00'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Pulse (xxx)

Audit	User	Time (GMT)
User entered '60'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:04

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:51:18
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' answered with 'PER PROTOCOL 8.2.5 VITAL SIGN MEASUREMENTS "On Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection (before participants are discharged from the study site)." THANK YOU.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 21:26:48
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:34:56
User entered '17:17'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 17:17'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '135'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '71'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:06:34

US3322199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:46

US3322199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:46

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '16:42'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 16:42'	System	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 21:48:04

US3322199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

US3322199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

US3322199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:18'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

US3322199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 16:18'	System	03 Sep 2020 15:07:10

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 16:15'	System	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 15:07:31

US3322199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:36

US3322199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:07:36

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:20:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered 'Yes (Y)'	System	02 Sep 2020 22:21:32

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered '97.2'	System	02 Sep 2020 22:21:32

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered 'No (N)'	System	02 Sep 2020 22:21:32

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 22:21:32

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered 'Yes (Y)'	System	03 Sep 2020 03:13:40

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered '97.8'	System	03 Sep 2020 03:13:40

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered 'No (N)'	System	03 Sep 2020 03:13:40

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered '02 Sep 2020 22:13'	System	03 Sep 2020 03:13:40

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered 'Yes (Y)'	System	04 Sep 2020 04:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered '97.4'	System	04 Sep 2020 04:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered 'No (N)'	System	04 Sep 2020 04:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered '03 Sep 2020 23:31'	System	04 Sep 2020 04:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:17:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered 'Yes (Y)'	System	04 Sep 2020 23:18:26

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:07', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered '97.6'	System	04 Sep 2020 23:18:26

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered 'No (N)'	System	04 Sep 2020 23:18:26

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 23:18:26

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered 'Yes (Y)'	System	06 Sep 2020 03:08:05

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered '98.1'	System	06 Sep 2020 03:08:05

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered 'No (N)'	System	06 Sep 2020 03:08:05

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:05

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered 'Yes (Y)'	System	06 Sep 2020 23:38:46

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered '98.3'	System	06 Sep 2020 23:38:46

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered 'No (N)'	System	06 Sep 2020 23:38:46

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:46

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:21

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered '98.2'	System	08 Sep 2020 00:02:21

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:16', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered 'No (N)'	System	08 Sep 2020 00:02:21

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:21

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:30:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered 'Yes (Y)'	System	08 Sep 2020 23:31:18

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered '97.8'	System	08 Sep 2020 23:31:18

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered 'No (N)'	System	08 Sep 2020 23:31:18

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:18

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'None (1)'	System	02 Sep 2020 22:22:18

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'No (N)'	System	02 Sep 2020 22:22:18

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'No (N)'	System	02 Sep 2020 22:22:18

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e' User entered 'None (1)'	System	02 Sep 2020 22:22:18
	System	02 Sep 2020 22:22:18

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered '02 Sep 2020 17:22'	System	02 Sep 2020 22:22:18

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'None (1)'	System	03 Sep 2020 03:14:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'No (N)'	System	03 Sep 2020 03:14:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'No (N)'	System	03 Sep 2020 03:14:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'None (1)'	System	03 Sep 2020 03:14:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered '02 Sep 2020 22:13'	System	03 Sep 2020 03:14:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'None (1)'	System	04 Sep 2020 04:31:53

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'No (N)'	System	04 Sep 2020 04:31:53

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'No (N)'	System	04 Sep 2020 04:31:53

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:48', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d' User entered 'None (1)'	System	04 Sep 2020 04:31:53
	System	04 Sep 2020 04:31:53

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered '03 Sep 2020 23:31'	System	04 Sep 2020 04:31:53

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:48', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'None (1)'	System	04 Sep 2020 23:19:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'No (N)'	System	04 Sep 2020 23:19:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'No (N)'	System	04 Sep 2020 23:19:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'None (1)'	System	04 Sep 2020 23:19:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 23:19:00

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'None (1)'	System	06 Sep 2020 03:08:19

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'No (N)'	System	06 Sep 2020 03:08:19

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'No (N)'	System	06 Sep 2020 03:08:19

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'None (1)'	System	06 Sep 2020 03:08:19

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:19

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'None (1)'	System	06 Sep 2020 23:38:57

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'No (N)'	System	06 Sep 2020 23:38:57

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'No (N)'	System	06 Sep 2020 23:38:57

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'None (1)'	System	06 Sep 2020 23:38:57

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:57

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d' User entered 'None (1)'	System	08 Sep 2020 00:02:36
	System	08 Sep 2020 00:02:36

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'No (N)'	System	08 Sep 2020 00:02:36

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'No (N)'	System	08 Sep 2020 00:02:36

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d' User entered 'None (1)'	System	08 Sep 2020 00:02:36
	System	08 Sep 2020 00:02:36

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:36

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'None (1)'	System	08 Sep 2020 23:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'No (N)'	System	08 Sep 2020 23:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'No (N)'	System	08 Sep 2020 23:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'None (1)'	System	08 Sep 2020 23:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:29

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea' User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea' User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea' User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'No (N)'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered '02 Sep 2020 17:22'	System	02 Sep 2020 22:22:47

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'No (N)'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered '02 Sep 2020 22:14'	System	03 Sep 2020 03:14:57

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'No (N)'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered '03 Sep 2020 23:32'	System	04 Sep 2020 04:32:37

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'No (N)'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered '04 Sep 2020 18:19'	System	04 Sep 2020 23:19:26

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'No (N)'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:40

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:07', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'No (N)'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered '06 Sep 2020 18:39'	System	06 Sep 2020 23:39:29

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:51

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'No (N)'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:48

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

US3322199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

US3322199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

US3322199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

US3322199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

US3322199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:39

US3322199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 17:53:39

US3322199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

US3322199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

US3322199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

US3322199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

US3322199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:19

US3322199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 18:51:19

US3322199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

US3322199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

US3322199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

US3322199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

US3322199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:37

US3322199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 16:17:37

US3322199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

US3322199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

US3322199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

US3322199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	01 Oct 2020 22:05:49

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '11:15'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:15'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '12:24'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 12:24'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 22:07:58

US3322199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:08:04

US3322199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:08:04

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '11:52'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:52'	System	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 16:58:12

US3322199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

US3322199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

US3322199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '11:40'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

US3322199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:40'	System	01 Oct 2020 22:09:48

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:35'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:35'	System	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 22:10:15

US3322199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:10:18

US3322199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 22:10:18

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered 'Yes (Y)'	System	01 Oct 2020 17:28:33

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83' User entered '98.2'	System	01 Oct 2020 17:28:33
	System	01 Oct 2020 17:28:33

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered 'No (N)'	System	01 Oct 2020 17:28:33

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:28', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered '01 Oct 2020 12:28'	System	01 Oct 2020 17:28:33

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:01:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered 'Yes (Y)'	System	02 Oct 2020 00:02:37

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e' User entered '98.1'	System	02 Oct 2020 00:02:37

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered 'No (N)'	System	02 Oct 2020 00:02:37

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered '01 Oct 2020 19:02'	System	02 Oct 2020 00:02:37

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:00:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered 'Yes (Y)'	System	03 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered '97.8'	System	03 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered 'No (N)'	System	03 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered 'Yes (Y)'	System	04 Oct 2020 00:43:29

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de' User entered '98.2'	System	04 Oct 2020 00:43:29

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered 'No (N)'	System	04 Oct 2020 00:43:29

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered '03 Oct 2020 19:43'	System	04 Oct 2020 00:43:29

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered 'Yes (Y)'	System	05 Oct 2020 01:32:44

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115' User entered '98.3'	System	05 Oct 2020 01:32:44
	System	05 Oct 2020 01:32:44

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered 'No (N)'	System	05 Oct 2020 01:32:44

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115' User entered '04 Oct 2020 20:32'	System	05 Oct 2020 01:32:44
	System	05 Oct 2020 01:32:44

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:00:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered 'Yes (Y)'	System	06 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered '97.8'	System	06 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered 'No (N)'	System	06 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:16

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered 'Yes (Y)'	System	07 Oct 2020 00:02:01

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered '98.4'	System	07 Oct 2020 00:02:01

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered 'No (N)'	System	07 Oct 2020 00:02:01

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8' User entered '06 Oct 2020 19:01'	System	07 Oct 2020 00:02:01
	System	07 Oct 2020 00:02:01

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered 'Yes (Y)'	System	08 Oct 2020 00:48:48

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered '98.1'	System	08 Oct 2020 00:48:48

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered 'No (N)'	System	08 Oct 2020 00:48:48

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered '07 Oct 2020 19:48'	System	08 Oct 2020 00:48:48

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e' User entered 'None (1)'	System	01 Oct 2020 17:28:48
	System	01 Oct 2020 17:28:48

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered 'No (N)'	System	01 Oct 2020 17:28:48

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e' User entered 'No (N)'	System	01 Oct 2020 17:28:48

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e' User entered 'None (1)'	System	01 Oct 2020 17:28:48
	System	01 Oct 2020 17:28:48

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered '01 Oct 2020 12:28'	System	01 Oct 2020 17:28:48

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'None (1)'	System	02 Oct 2020 00:03:28

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'No (N)'	System	02 Oct 2020 00:03:28

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'No (N)'	System	02 Oct 2020 00:03:28

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'None (1)'	System	02 Oct 2020 00:03:28

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered '01 Oct 2020 19:03'	System	02 Oct 2020 00:03:28

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'None (1)'	System	03 Oct 2020 00:01:30

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'No (N)'	System	03 Oct 2020 00:01:30

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'No (N)'	System	03 Oct 2020 00:01:30

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'None (1)'	System	03 Oct 2020 00:01:30

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:30

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'None (1)'	System	04 Oct 2020 00:43:40

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'No (N)'	System	04 Oct 2020 00:43:40

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'No (N)'	System	04 Oct 2020 00:43:40

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'None (1)'	System	04 Oct 2020 00:43:40

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered '03 Oct 2020 19:43'	System	04 Oct 2020 00:43:40

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'None (1)'	System	05 Oct 2020 01:32:52

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'No (N)'	System	05 Oct 2020 01:32:52

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'No (N)'	System	05 Oct 2020 01:32:52

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'None (1)'	System	05 Oct 2020 01:32:52

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered '04 Oct 2020 20:32'	System	05 Oct 2020 01:32:52

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f' User entered 'None (1)'	System	06 Oct 2020 00:01:27
	System	06 Oct 2020 00:01:27

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered 'No (N)'	System	06 Oct 2020 00:01:27

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f' User entered 'No (N)'	System	06 Oct 2020 00:01:27

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f' User entered 'None (1)'	System	06 Oct 2020 00:01:27

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f' User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:27
	System	06 Oct 2020 00:01:27

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'None (1)'	System	07 Oct 2020 00:02:13

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'No (N)'	System	07 Oct 2020 00:02:13

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'No (N)'	System	07 Oct 2020 00:02:13

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'None (1)'	System	07 Oct 2020 00:02:13

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered '06 Oct 2020 19:02'	System	07 Oct 2020 00:02:13

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'None (1)'	System	08 Oct 2020 00:49:05

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'No (N)'	System	08 Oct 2020 00:49:05

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'No (N)'	System	08 Oct 2020 00:49:05

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'None (1)'	System	08 Oct 2020 00:49:05

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered '07 Oct 2020 19:49'	System	08 Oct 2020 00:49:05

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'No (N)'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered '01 Oct 2020 12:29'	System	01 Oct 2020 17:29:33

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'No (N)'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered '01 Oct 2020 19:04'	System	02 Oct 2020 00:04:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'No (N)'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:43

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'No (N)'	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:44:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7' User entered '03 Oct 2020 19:44'	System	04 Oct 2020 00:44:02
	System	04 Oct 2020 00:44:02

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:33:01', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'No (N)'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:33:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered '04 Oct 2020 20:33'	System	05 Oct 2020 01:33:05

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9' User entered 'None (0)'	System	06 Oct 2020 00:01:53
	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'No (N)'	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9' User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:53
	System	06 Oct 2020 00:01:53

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'No (N)'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered '06 Oct 2020 19:02'	System	07 Oct 2020 00:02:34

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

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 (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'No (N)'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered '07 Oct 2020 19:49'	System	08 Oct 2020 00:49:24

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

US3322199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

US3322199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

US3322199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 06:31:49
User entered '13 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	13 Oct 2020 15:04:12
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple unsuccessful attempts made and left unanswered' (Site from System).	Elisa Moralez (b) (4)	13 Oct 2020 14:27:42
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Oct 2020 14:27:25
User entered '12 Oct 2020'	Elisa Moralez (b) (4)	13 Oct 2020 14:27:25

US3322199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 15:04:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

US3322199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'MULTIPLE UNSUCCESSFUL ATTEMPTS, patient finally responded on 13-Oct-2020, out of window' reason for change: Data Entry Error	Elisa Moralez (b) (4)	13 Oct 2020 15:04:12
User entered 'multiple unsuccessful attempts'	Elisa Moralez (b) (4)	13 Oct 2020 14:27:25

US3322199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:49

US3322199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 14:27:49

US3322199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

US3322199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

US3322199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

US3322199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

US3322199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 13:47:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 13:47:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:47:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 13:46:57
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:46:57

US3322199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 13:47:03
User entered empty.	System	16 Oct 2020 13:46:57

US3322199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

US3322199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

US3322199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

US3322199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

US3322199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:49

US3322199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:30:49

US3322199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

US3322199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

US3322199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

US3322199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	30 Oct 2020 20:41:55

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '11:19'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:19'	System	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '47'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 20:42:48

US3322199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:42:59

US3322199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:42:59

US3322199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

US3322199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

US3322199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '11:45'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

US3322199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:45'	System	30 Oct 2020 20:43:09

US3322199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:43:15

US3322199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 20:43:15

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 64'	System	02 Sep 2020 21:48:04

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045'	System	02 Nov 2020 21:48:54
User entered 'No (N)'	System	02 Nov 2020 21:48:54

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045'	System	02 Nov 2020 21:48:54
User entered 'No (N)'	System	02 Nov 2020 21:48:54

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045' User entered '02 Nov 2020 15:48:50'	System	02 Nov 2020 21:48:54
	System	02 Nov 2020 21:48:54

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 21:48:04

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 21:48:04

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '30 Oct 2020 00:01'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '03 Nov 2020 23:59'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '06 Nov 2020 00:01'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '10 Nov 2020 23:59'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 02:58:27

US3322199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:27
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 02:58:27

US3322199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:12:12

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:24
User entered 'USA-US060-2020-mRNA-1273-P301000012'	System	23 Nov 2020 23:35:05
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 23:35:05

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:52
Data point term sent to Coder	System	21 Nov 2020 00:08:02
Coding entries removed.	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User entered 'Fatal Myocardial Infarction' reason for change: New Information	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:39:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:39:03
Data point term sent to Coder	System	20 Nov 2020 22:38:07
User entered 'myocardial infarction' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:37:16
Data point term sent to Coder	System	20 Nov 2020 22:13:41
User entered 'Massive Heart Attack'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Death](#)

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[None](#)

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Fatal (FATAL)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'SAE Term: Myocardial Infarction Outcome: Fatal Causality: Not IP related Vaccination #1: 02-SEP-2020 Vaccination #2: 01-OCT-2020 C3: 30-OCT-2020	(b) (4), (b) (6)	21 Nov 2020 00:07:53
Subject's sister called our site to inform that subject passed away on 16-NOV-2020 from a massive heart attack. Subject had multiple cardiac risk factors including hypertension (2018), pre-diabetes (2019), Supraventricular tachycardia (2019), obesity, hyperlipidemia (2019), left bundle branch block (1976). Further details not available. Medical records being requested there is insufficient information to determine if there were any new concomitant medications, non-study vaccinations, prohibited medications, or COVID symptoms. Does not appear to be COVID-19 related since subject's sister reported a major heart attack. Medical records pending.' reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 22:13:33

US3322199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 00:07:53

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:14:46

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 00:05:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 00:05:34
Data point term sent to Coder	System	25 Sep 2020 20:15:34
User entered 'Atenolol'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'Arythmia/Hypertension'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:13:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4)	19 Oct 2020 21:14:55
User entered 'UN Jan 2019' reason for change: Data Entry Error	Elisa Moralez (b) (4)	19 Oct 2020 21:14:47
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:25:54
User entered 'un Jan 2017'	Elisa Moralez (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:23:55
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:15:13

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
Data point term sent to Coder	System	25 Sep 2020 20:16:34
User entered 'Amlodipine'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'un Oct 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:24:09
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:15:39

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:16:46
Data point term sent to Coder	System	25 Sep 2020 20:16:35
User entered 'Aspirin'	Elisa Moralez (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cardiac prophylaxis'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:16:00

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:04:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:04:56
Data point term sent to Coder	System	25 Sep 2020 20:16:35
User entered 'Atorvastatin'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:13:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'will update per updated source now' (Site from DM).	Elisa Moralez (b) (4)	19 Oct 2020 21:15:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:26:49
User entered 'Hypercholesteremia'	Elisa Moralez (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:16:29

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 20:16:29

US3322199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:04

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:05

US3322199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:04

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Death (DEATH)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:05

US3322199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:05

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered 'Death (DEATH)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

If reason for discontinuation is [Death](#), main cause of death

Audit	User	Time (GMT)
User entered 'Adverse event (ADVERSE EVENT)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:04

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNK)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'USA-US060-2020-MRNA-1273-P301000012'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Veronica'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Fragoso'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '6550 Mapleridge Street'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Houston'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'TX'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '77081'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 23:35:44

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 23:35:44

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'USA-US060-2020-MRNA-1273-P301000012'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

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

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Veronica'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Fragoso'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '6550 Mapleridge Street'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Houston'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'TX'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '77081'	System	23 Nov 2020 23:35:05

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 23:35:44

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 23:35:44

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 18:35'	System	23 Nov 2020 23:35:44

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 23:35:44