

US3402299 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:26:40

All time stamps listed in this document are displayed in GMT

US3402299

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:40

[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 09:26:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

Condition	GASTRIC BYPASS ROUX-EN-Y
Start date (dd MMM yyyy)	10 NOV 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	10 NOV 2010
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2010
Start Year (derived)	2010
Stop Month and Year (derived)	NOV 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN JUL 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN JUL 1990
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JUL 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

Condition	CHRONIC CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

Condition	ALLERGY TO AMOXYCILLAN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

Condition	ABNORMAL PANNUS. ABDOMINAL FAT APRON
Start date (dd MMM yyyy)	10 NOV 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	26 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2010
Start Year (derived)	2010
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:00 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 13:00
Height (<i>xxx.x</i>)	160.2 cm
Weight (<i>xxx.x</i>)	77.2 kg
BMI (<i>xxx.x</i>)	30.08100 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☒
	Post-menopausal ☐
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN UNK 2003
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐	No ☒
Other	Yes ☐	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 102389

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 09:26:40

Height	
Weight	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Height	
Weight	
Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 13:20
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 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 09:26:40

Height	
Weight	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 14:39
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

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 09:26:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 AUG 2020

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 14:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

08 AUG 2020

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

13:59 (24 HR)

Collection date and time (derived)

08 AUG 2020 13:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:40

Collection date (<i>dd MMM yyyy</i>)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:56	08 AUG 2020 13:56
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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 09:26:40

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 08 AUG 2020 14:30

PC Open Date & Time 08 AUG 2020 14:28

PC Close Date & Time 08 AUG 2020 16:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 98.2 °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	08 AUG 2020 21:28
PC Open Date & Time	08 AUG 2020 17:53
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

97.6 °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

09 AUG 2020 20:38

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

11 AUG 2020 19:50

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

97.2 °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 12 AUG 2020 20:56

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

99.1 °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

13 AUG 2020 21:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

08 AUG 2020 14:30

PC Open Date & Time

08 AUG 2020 14:28

PC Close Date & Time

08 AUG 2020 16:58

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

08 AUG 2020 21:28

PC Open Date & Time

08 AUG 2020 17:53

PC Close Date & Time

09 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

09 AUG 2020 20:37

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

10 AUG 2020 20:28

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

11 AUG 2020 19:49

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

12 AUG 2020 20:56

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

13 AUG 2020 21:07

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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

14 AUG 2020 21:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 ☐

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 14:31
PC Open Date & Time	08 AUG 2020 14:28
PC Close Date & Time	08 AUG 2020 16:58

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 ☐

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 21:28
PC Open Date & Time	08 AUG 2020 17:53
PC Close Date & Time	09 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	09 AUG 2020 20:38
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	10 AUG 2020 20:29
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	11 AUG 2020 19:50
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	12 AUG 2020 20:56
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	13 AUG 2020 21:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	14 AUG 2020 21:23
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 15 AUG 2020 19:22

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 16 AUG 2020 20:56

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 17 AUG 2020 16:47

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 AUG 2020 19:22
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 AUG 2020 20:56
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 AUG 2020 16:47
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

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

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:08
Temperature (xxx.x)	97.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:12
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	10 SEP 2020
What was the treatment time? (00:00-23:59)	11:41 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 11:41
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:28 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:28

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:40

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	10 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

US3402299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

98.1 °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

10 SEP 2020 12:13

PC Open Date & Time

10 SEP 2020 12:01

PC Close Date & Time

10 SEP 2020 14:31

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 98.2 °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	10 SEP 2020 22:42
PC Open Date & Time	10 SEP 2020 15:26
PC Close Date & Time	11 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

97.6 °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

11 SEP 2020 19:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:38

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

96.8 °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

14 SEP 2020 19:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

16 SEP 2020 00:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:14

PC Open Date & Time

10 SEP 2020 12:01

PC Close Date & Time

10 SEP 2020 14:31

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

10 SEP 2020 22:41

PC Open Date & Time

10 SEP 2020 15:26

PC Close Date & Time

11 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

11 SEP 2020 19:58

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

12 SEP 2020 21:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

13 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

14 SEP 2020 19:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 00:11

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 23:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 ☐

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:14
PC Open Date & Time	10 SEP 2020 12:01
PC Close Date & Time	10 SEP 2020 14:31

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 ☐

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 22:42
PC Open Date & Time	10 SEP 2020 15:26
PC Close Date & Time	11 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	11 SEP 2020 19:59
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	12 SEP 2020 21:38
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	13 SEP 2020 22:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	14 SEP 2020 19:41
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 ☒

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

Yes ☐	
PC Time stamp	16 SEP 2020 23:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3402299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:04 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 16:04
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

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.

US3402299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	15 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:06 (24 HR)
Collection date and time (derived)	15 OCT 2020 16:06

US3402299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
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 ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 12:47:08
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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 ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 OCT 2020 06:19:30

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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 ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

05 NOV 2020 16:14:46

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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 ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

14 NOV 2020 15:01:17

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

05 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

12 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

19 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

26 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

02 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

09 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

16 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
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 ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 00:02:00
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

14 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

21 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

28 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

04 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

11 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

18 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

25 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

01 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

08 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

15 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

22 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

01 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

08 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

15 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

22 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

19 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

26 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

08 NOV 2021 00:01

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12 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

15 NOV 2021 00:01

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19 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

03 JAN 2022 00:01

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07 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

10 JAN 2022 00:01

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14 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

25 APR 2022 00:01

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29 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

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06 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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16 MAY 2022 00:01

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20 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

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27 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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03 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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06 JUN 2022 00:01

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10 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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13 JUN 2022 00:01

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17 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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20 JUN 2022 00:01

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24 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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08 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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15 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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

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18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
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 ☐ Yes ☐
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 ☐
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 ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
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 ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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 ☐ Yes ☐

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 ☐

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 ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

US3402299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402299

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:40

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

US3402299

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:26:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

AEID	USA-US059-2020-MRNA-1273-P30 1000003
Adverse event	POST OPERATIVE BLEEDING
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	01 SEP 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	4

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

SUBJECT WENT IN HOSPITAL
FOR ROUTINE
PANNICULECTOMY. AFTER
THE PROCEDURE THE
PATIENTS HOSPITAL COURSE
WAS COMPLICATED BY
HYPOTENSION. SHE RECEIVED
2.5L OF FLUID. A "RAPID
RESPONSE WAS CALLED ON
27AUG2020 FOR PATIENTS
HYPOTENSION. PATIENT WAS
TAKEN BACK TO THE OR FOR A
POSSIBLE POST OPERATIVE
BLEED. 2-3 SMALL ATREIAL
PERFORATIONS WERE
CAUTERIZED ON RECTUS
FASCIA, AND A SMALL
AMOUNT OF OOZING FROM
SURROUNDING MUSCLE WAS
SEEN. THE PATIENT RECEIVED
2 UNITS OF PACKED RED
BLOOD CELLS.
INTRAOPERATIVELY. PATIENT
REMAINED HYPOTENSIVE, AND
WAS GIVEN AN ADDITIONAL 2
UNITS PF PACKED RED BLOOD
CELLS. SHE WAS THEN
TRANSFERRED TO ICU AND
GIVEN AN ADDITIONAL FLUID
BOLUS. SUBJECTS
HEMAGLOBIN AND
HEMATOCRIT WENT FROM
10.0/31.1L 27AUG2020 AT 07:18
TO 7.7/23.5 27AUG2020 AT 11:26
TO 9.1/28.2L 28/AUG AT
04:22.SUBJECT ALSO HAD CT OF
THE ABDOMEN AND PELVIS

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

WHICH WAS RELATIVELY
NORMAL.

SUBJECT ALSO HAD A CT
ANGIOGRAPHY OF THE CHEST
TO RULE OUT PULMONARY
EMBOLISM. NO PULMINARY
EMBOLI WERE FOUND. CHEST
X-RAY 29AUG2020 NORMAL.
ABDOMINAL X-RAY NORMAL.

AFTER SIGNIFICANT
RECOVERY PATIENT WAS
DISCHARGED 01SEP2020.

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)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

AEID	
Adverse event	SEVERE HEADACHE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	11 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:40

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

Yes ☒

No ☐

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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	TRAZADONE
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	LACTULOSE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
Dose per administration	10
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	SUMITRIPTAN (IMITREX)
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINES
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	DULOXETINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	CLONAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY/DEPRESSION
Dose per administration	0.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	VITAMIN B12
Prophylaxis	Yes ☒ No ☐
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☒ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☒
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	LUBIPROSTONE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
Dose per administration	24
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINE HEADACHES
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		15 AUG 2020
Was this medication taken for solicited event?	Yes ☒	No ☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	METOCLOPRAMIDE HCL
Prophylaxis	Yes ☐ No ☒
Indication	PANNUS OF ABDOMINAL AREA
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	ONDANSETRON
Prophylaxis	Yes ☐ No ☒
Indication	IDIOPATHIC ABDOMINAL PANNUS
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 2010	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	4 UNITS PACKED RED BLOOD CELLS
Prophylaxis	Yes ☐ No ☒
Indication	POST OPERATIVE BLEEDING
Dose per administration	1000
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	29 AUG 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	INFLUENZA VACCINATION
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS FOR INFLUENZA
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		15 AUG 2020
Was this medication taken for solicited event?	Yes ☒	No ☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:40

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:26:40

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

US3402299

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:40

Date of dosing discontinuation (dd MMM yyyy)

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

US3402299

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:26:40

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:40

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/SEP/2020 13:07
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

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:40

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/SEP/2020 16:03
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

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:40

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/OCT/2020 14:13
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

US3402299 (Prod: Meridian Clinical Research, LLC)

US3402299

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402299'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Aug 2020 17:35:25

US3402299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 18:23:11

US3402299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:23
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:35:26

US3402299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Aug 2020 18:23:11

US3402299

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	08 Aug 2020 18:23:11

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 17:35:27

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Age](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:59:16
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:59:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

If reason for screen fail is [Other](#), specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:34:42
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:35:26

US3402299

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:35:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:35:25
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:39:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
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)	06 Oct 2020 14:47:52
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 'OBESITY' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Sep 2020 16:48:17
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)	28 Sep 2020 18:00:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:12:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:12:23
Data point term sent to Coder	System	08 Aug 2020 21:40:56
User entered 'GASTRIC BYPASS ROUX-EN-Y'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Traci Hull (b) (4)	08 Aug 2020 21:40:21
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:40:21
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:40:21
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Traci Hull (b) (4)	08 Aug 2020 21:40:21
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:40:21
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Nov 2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Nov 2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:41:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:41:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:40:57
User entered 'CHOLECYSTECTOMY'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 1990'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 1990'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:40:52
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jul 1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jul 1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:41:57
User entered 'CHRONIC CONSTIPATION'	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2010'	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:06
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2010'	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:41:58
User entered 'INSOMNIA'	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2000'	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:19
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2000'	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:41:58
User entered 'HYPOTHYROIDISM'	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2008'	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:34
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2008'	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:42:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:41:58
User entered 'MIGRAINE'	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 1988'	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:41:48
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1988'	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:42:59
User entered 'ANXIETY'	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2018'	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:02
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2018'	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:42:59
User entered 'DEPRESSION'	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2018'	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:13
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2018'	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
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: Drug allergy - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:58:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:58:26
	(b) (4)	
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: Drug allergy - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 14:04:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 14:04:08
	(b) (4)	
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: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 16:26:15
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 16:26:15
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:42:59
User entered 'ALLERGY TO AMOXYCILLAN'	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 1990'	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:35
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1990'	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User closed query 'Per DM CLR: Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF, by adding the cause (condition) to the list of condition the patient has.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:56:21
Query 'Per DM CLR: Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF, by adding the cause (condition) to the list of condition the patient has.' answered with 'CALLED SPOKE TO PATIENT STATED SHE HAD A COMPLETE HYSTERECTOMY DUE TO HEAVY MENSTRAL CYCLE AND CRAMPING. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Oct 2020 14:44:35
User opened query 'Per DM CLR: Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF, by adding the cause (condition) to the list of condition the patient has.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:03:14
User closed query 'Per DM CLR: RQ: Response noted. However, please review and record the underlying medical condition as separate entry. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:02:49
Query 'Per DM CLR: RQ: Response noted. However, please review and record the underlying medical condition as separate entry. Otherwise, clarify in query response. ' answered with 'CANCEROUS CYSTS, EXCESSIVE BLEEDING' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:12:07
User opened query 'Per DM CLR: RQ: Response noted. However, please review and record the underlying medical condition as separate entry. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 04:30:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:40

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:43:50
Data point term sent to Coder	System	08 Aug 2020 21:43:00
User entered 'COMPLETE HYSTERECTOMY'	Traci Hull (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2003'	Traci Hull (b) (4)	08 Aug 2020 21:42:51
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:51
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User closed query 'Per CDM: Response noted. However, please confirm if COMPLETE HYSTERECTOMY is currently ONGOING as it is unusual for this procedure to be ongoing and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:02:47
Query 'Per CDM: Response noted. However, please confirm if COMPLETE HYSTERECTOMY is currently ONGOING as it is unusual for this procedure to be ongoing and update as appropriate. Thank you.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:11:32
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:11:22
User opened query 'Per CDM: Response noted. However, please confirm if COMPLETE HYSTERECTOMY is currently ONGOING as it is unusual for this procedure to be ongoing and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:49:11
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:49:11
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' answered with 'ELECTIVE DUE TO EXCESSIVE MENSTRATION AND BILATERAL OVARIAN CYSTS' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Sep 2020 16:53:42
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:01:14
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2003' reason for change:	Tammy Kohn (b) (4)	08 Oct 2020 14:11:22
Data Entry Error	(b) (4)	
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:42:51
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:42:51
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2003'	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	08 Oct 2020 14:11:22
User entered empty.	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2003'	System	08 Oct 2020 14:11:22
User entered empty.	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:44:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 21:44:50
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 21:44:00
User entered 'RIGHT WRIST FRACTURE'	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 2020'	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:43:12
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal wall conditions NEC, PT: Abdominal fat apron, LLT: Abdominal fat apron - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 14:51:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 14:51:40
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 16:30:37
User closed query 'For coding purposes, please clarify/provide more information for ABNORMAL PANNUS. Is Pendulous abdomen, Abdominal fat apron or something else. Update the term with your response.' (Site from System).	System	21 Oct 2020 16:30:13
Query 'For coding purposes, please clarify/provide more information for ABNORMAL PANNUS. Is Pendulous abdomen, Abdominal fat apron or something else. Update the term with your response.' answered with 'ABDOMINAL FAT APRON' (Site from System).	Traci Hull (b) (4)	21 Oct 2020 16:30:13
	(b) (4)	
Coding entries removed.	Traci Hull (b) (4)	21 Oct 2020 16:30:03
	(b) (4)	
User entered 'ABNORMAL PANNUS. ABDOMINAL FAT APRON' reason for change: Per Query Resolution	Traci Hull (b) (4)	21 Oct 2020 16:30:03
	(b) (4)	
User opened query 'For coding purposes, please clarify/provide more information for ABNORMAL PANNUS. Is Pendulous abdomen, Abdominal fat apron or something else. Update the term with your response.' (Site from System).	Coder Import (b) (4)	18 Oct 2020 13:55:18
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial disorder, LLT: Synovial disorder - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:25:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:25:19
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 14:33:52

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

[Condition](#)

Audit	User	Time (GMT)
User closed query 'DM-Coding: Please enter the location for ABNORMAL PANNUS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	08 Oct 2020 14:33:13
Query 'DM-Coding: Please enter the location for ABNORMAL PANNUS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'SUBJECT HAS NO KNOW CAUSE OF ABNORMAL PANNUS IDIOPATHIC ' (Site from System).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:33:13
Data point term sent to Coder	System	08 Oct 2020 14:32:50
User entered 'ABNORMAL PANNUS IDIOPATHIC' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:32:43
User opened query 'DM-Coding: Please enter the location for ABNORMAL PANNUS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:25:12
Data point term sent to Coder	System	02 Oct 2020 17:19:09
User entered 'Abnormal pannus'	Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 17:18:41

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:19:00
User entered 'No (N)' reason for change: New Information	Jennifer Molstead (b) (4)	02 Oct 2020 17:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:18:41
User entered empty.	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:17:59
User closed query 'Per source - stop date is 26 Aug 2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:17:57
Query 'Per source - stop date is 26 Aug 2020. Please verify and update accordingly. ' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	09 Nov 2020 22:53:17
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	09 Nov 2020 22:53:11
	(b) (4)	
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	09 Nov 2020 22:53:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User opened query 'Per source - stop date is 26 Aug 2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 00:41:24
User entered '01 Sep 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 16:15:00
	(b) (4)	
User entered '21 Sep 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 16:14:20
	(b) (4)	
User entered '26 Aug 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:54
	(b) (4)	
User entered '02 Aug 2020'	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41
	(b) (4)	

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Nov 2010'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	09 Nov 2020 22:53:11
User entered 'Sep 2020'	System	05 Oct 2020 16:14:20
User entered 'Aug 2020'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:00:00
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:00:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered '13:00'	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 13:00'	System	11 Nov 2020 13:00:00
User entered '8 Aug 2020 13:00'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered '160.2' cm	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	
DataPoint set to visible.	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered '77.2' kg	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	
DataPoint set to visible.	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '30.08100'	System	16 Sep 2020 23:48:56
User entered '30.1'	System	08 Aug 2020 21:43:53
DataPoint set to visible.	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	08 Aug 2020 21:43:53
DataPoint set to visible.	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User closed query 'Per CDM re-query: To avoid duplication of data CCGs pg 16-17 suggests to record ND. Please remove the data from Temperature data field and enter ND - NOT DONE.' (Site from DM). Query 'Per CDM re-query: To avoid duplication of data CCGs pg 16-17 suggests to record ND. Please remove the data from Temperature data field and enter ND - NOT DONE.' answered with 'NOT DONE' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:55:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 13:21:15
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly' (Site from DM).	(b) (4)	09 Oct 2020 13:20:55
User opened query 'Per CDM re-query: To avoid duplication of data CCGs pg 16-17 suggests to record ND. Please remove the data from Temperature data field and enter ND - NOT DONE.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:56:53
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:56:51
User entered '37.1' C reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Oct 2020 21:06:31
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly' (Site from DM).	(b) (4)	08 Oct 2020 21:06:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:46:57
	(b) (4), (b) (6)	06 Oct 2020 14:46:44

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:41:39
User entered '37.1' C	Traci Hull (b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 13:21:03
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 21:06:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 21:06:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Oct 2020 21:06:36
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 21:06:24
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:41:39
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:43:53
	(b) (4)	

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User closed query 'Per CDM: Thank you for removing the data. However as per CCGs, to avoid missing data on this form, Pulse, Respiratory Rate, Systolic BP and Diastolic BP should be recorded as ND - NOT DONE. Please enter ND - NOT DONE in the data field of EDC. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:55:47
Query 'Per CDM: Thank you for removing the data. However as per CCGs, to avoid missing data on this form, Pulse, Respiratory Rate, Systolic BP and Diastolic BP should be recorded as ND - NOT DONE. Please enter ND - NOT DONE in the data field of EDC. Thank you' answered with 'NOT DONE' (Site from DM).	Tammy Kohn (b) (4)	09 Oct 2020 13:21:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 13:20:55
User opened query 'Per CDM: Thank you for removing the data. However as per CCGs, to avoid missing data on this form, Pulse, Respiratory Rate, Systolic BP and Diastolic BP should be recorded as ND - NOT DONE. Please enter ND - NOT DONE in the data field of EDC. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:03:06
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:53:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:46:33
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:19

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 17:41:01
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:41:01
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:44:35
User entered '66'	Traci Hull (b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 13:20:55
User entered empty.	System	02 Oct 2020 17:41:01
User entered 'bpm'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 13:20:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:46:35
User opened query 'Data is required. Please provide.' System	Tammy Kohn (b) (4)	02 Oct 2020 17:41:16
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '18'	Traci Hull (b) (4)	02 Oct 2020 17:41:01
	(b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 13:20:55
User entered empty.	System	02 Oct 2020 17:41:01
User entered 'breaths/min'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 13:20:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:46:37
User opened query 'Data is required. Please provide.' System	Tammy Kohn (b) (4)	02 Oct 2020 17:41:21
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '100'	Traci Hull (b) (4)	02 Oct 2020 17:41:01
	(b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 13:20:55
User entered empty.	System	02 Oct 2020 17:41:01
User entered 'mmHg'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 13:20:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 14:46:38
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 17:41:24
User opened query 'Data is required. Please provide.' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:01
User entered empty; reason for change Data Entry Error	System	02 Oct 2020 17:41:01
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Tammy Kohn (b) (4)	24 Sep 2020 17:44:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS. NOT CLINICALLY SIGNIFICANT. PLEASE ADVISE ON QUERY RESOLUTION' (Site from System).	(b) (4)	23 Sep 2020 18:24:04
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Traci Hull (b) (4)	16 Sep 2020 23:48:56
User entered '58'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 13:20:55
User entered empty.	System	02 Oct 2020 17:41:01
User entered 'mmHg'	System	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:40
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:44:12
	(b) (4)	

US3402299

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:32:58
Comment added 'SAME DATE'.	Traci Hull (b) (4)	11 Sep 2020 18:42:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Sep 2020 18:42:18
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:42:18
User entered '08 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	11 Sep 2020 18:42:18
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	10 Sep 2020 15:56:03
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:44:12

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:00:16
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:03:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 13:03:29
User entered '8 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Aug 2020 13:03:29
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:44:38
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'Surgically sterile (SURGICALLY STERILE)'	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'UN UNK 2003'	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

[Date of surgery unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:44:38
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered '1'	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:40

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:45:12
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:18
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:45:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:20
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:18
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:45:25
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:18
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	08 Aug 2020 21:45:25
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	08 Aug 2020 21:45:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:40:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:07:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:07:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 17:40:24
User entered '102389' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:40:24

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:40:24

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:36
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:36
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:45:36
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:43:57
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:55:52
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	02 Nov 2020 13:26:21
User entered 'No (N)'	(b) (4)	
	Tammy Kohn (b) (4)	02 Nov 2020 13:26:13
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:47:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:04:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:38:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:04
User closed query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:04:31
Query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' answered with 'ND NOT DONE' (Site from DM).	Tammy Kohn (b) (4)	08 Oct 2020 21:06:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:28
User opened query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:27
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	02 Oct 2020 17:42:18
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:44:46
User entered '160.2' cm	Traci Hull (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
User entered '77.2' kg	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:04
User closed query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:04:31
Query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' answered with 'ND NOT DONE' (Site from DM).	Tammy Kohn (b) (4)	08 Oct 2020 21:06:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:28
User opened query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:27
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	02 Oct 2020 17:42:18
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:44:46
User entered '160.2' cm	Traci Hull (b) (4)	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
User entered '77.2' kg	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:44
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '13:20'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 13:20'	System	11 Nov 2020 13:01:44
User entered '8 Aug 2020 13:20'	System	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '37.1' C	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Oral (Oral)'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '66'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '18'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '100'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 13:47:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NO CS/NCS OR AE PATIENT DIASTOLIC BLOOD PRESURE IS CORRECT' (Site from System).	Tammy Kohn (b) (4)	21 Sep 2020 13:37:19
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:48:56
User entered '58'	Traci Hull (b) (4)	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:04
User closed query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:04:31
Query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' answered with 'ND NOT DONE' (Site from DM).	Tammy Kohn (b) (4)	08 Oct 2020 21:06:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:28
User opened query 'Per CDM re-query: Thank you for removing the data. However in order to avoid missing data on this form, CCG indicates to record Height and Weight data field as ND - NOT DONE. Please enter ND - NOT DONE. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:27
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	02 Oct 2020 17:42:18
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:44:46
User entered '160.2' cm	Traci Hull (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:40

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
User entered '77.2' kg	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:44
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:45:50
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MINUTES' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 21:47:14
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		08 Aug 2020 21:47:04
User entered '14:39'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 14:39'	System	11 Nov 2020 13:01:44
User entered '8 Aug 2020 14:39'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '36.8' C	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Oral (Oral)'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '58'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '16'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '106'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '76'	Traci Hull (b) (4)	08 Aug 2020 21:47:04
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:52
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	10 Sep 2020 16:27:26
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:47:26
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:44:52
User entered empty; reason for change Data Entry Error	Traci Hull (b) (4)	10 Sep 2020 16:27:26
	(b) (4)	
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:47:26
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:58
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered '14:08'	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 14:08'	System	11 Nov 2020 13:01:58
User entered '8 Aug 2020 14:08'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered 'ONCE'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:47:42
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:02:09
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:02:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:47:42
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered '13:59'	Traci Hull (b) (4)	08 Aug 2020 21:47:42
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 13:59'	System	11 Nov 2020 13:02:09
User entered '8 Aug 2020 13:59'	System	08 Aug 2020 21:47:42

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:02:21
	(b) (4)	
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:02:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 21:48:06
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:06

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:48:06
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered '13:56'	Traci Hull (b) (4)	08 Aug 2020 21:48:06
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 13:56'	System	11 Nov 2020 13:02:21
User entered '8 Aug 2020 13:56'	System	08 Aug 2020 21:48:06

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:06

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:48:06
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:48:06
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:48:06

US3402299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:45:26
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 21:48:12
	(b) (4)	

US3402299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 21:48:12

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:29:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'ce72827f-b278-4dae-b6c9-fa7b0e01c8b1'	System	08 Aug 2020 18:30:06
User entered 'Yes (Y)'	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:29:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'ce72827f-b278-4dae-b6c9-fa7b0e01c8b1'	System	08 Aug 2020 18:30:06
User entered '98.2'	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'ce72827f-b278-4dae-b6c9-fa7b0e01c8b1'	System	08 Aug 2020 18:30:06
User entered 'No (N)'	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:04', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'ce72827f-b278-4dae-b6c9-fa7b0e01c8b1'	System	08 Aug 2020 18:30:06
User entered '08 Aug 2020 14:30'	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:58'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:27:22', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '2a3ee9e4-3a1b-4871-9192-f9e1126c2e14'	System	09 Aug 2020 01:28:02
User entered 'Yes (Y)'	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:27:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '2a3ee9e4-3a1b-4871-9192-f9e1126c2e14' User entered '98.2'	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:27:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '2a3ee9e4-3a1b-4871-9192-f9e1126c2e14'	System	09 Aug 2020 01:28:02
User entered 'No (N)'	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '2a3ee9e4-3a1b-4871-9192-f9e1126c2e14'	System	09 Aug 2020 01:28:02
User entered '08 Aug 2020 21:28'	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 17:53'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 2'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a0fe748d-e7e4-4241-b975-fa26dcff2128'	System	10 Aug 2020 00:38:56
User entered 'Yes (Y)'	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:46', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a0fe748d-e7e4-4241-b975-fa26dcff2128'	System	10 Aug 2020 00:38:56
User entered '97.6'	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a0fe748d-e7e4-4241-b975-fa26dcff2128'	System	10 Aug 2020 00:38:56
User entered 'No (N)'	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a0fe748d-e7e4-4241-b975-fa26dcff2128'	System	10 Aug 2020 00:38:56
User entered '09 Aug 2020 20:38'	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 3'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:02', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dd95ba6e-bacf-483c-a288-fedc00ba07dd'	System	11 Aug 2020 00:28:16
User entered 'Yes (Y)'	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dd95ba6e-bacf-483c-a288-fedc00ba07dd'	System	11 Aug 2020 00:28:16
User entered '97.9'	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:11', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dd95ba6e-bacf-483c-a288-fedc00ba07dd'	System	11 Aug 2020 00:28:16
User entered 'No (N)'	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dd95ba6e-bacf-483c-a288-fedc00ba07dd'	System	11 Aug 2020 00:28:16
User entered '10 Aug 2020 20:28'	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 4'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:27', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7598ebda-671f-4dd4-ab2b-0c7e3045f1b3'	System	11 Aug 2020 23:50:41
User entered 'Yes (Y)'	System	11 Aug 2020 23:50:41

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7598ebda-671f-4dd4-ab2b-0c7e3045f1b3' User entered '98.1'	System	11 Aug 2020 23:50:41
	System	11 Aug 2020 23:50:41

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7598ebda-671f-4dd4-ab2b-0c7e3045f1b3'	System	11 Aug 2020 23:50:41
User entered 'No (N)'	System	11 Aug 2020 23:50:41

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:39', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7598ebda-671f-4dd4-ab2b-0c7e3045f1b3'	System	11 Aug 2020 23:50:41
User entered '11 Aug 2020 19:50'	System	11 Aug 2020 23:50:41

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 5'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6c10bcc6-53f6-44f4-b895-26914572dfbe'	System	13 Aug 2020 00:56:53
User entered 'Yes (Y)'	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6c10bcc6-53f6-44f4-b895-26914572dfbe'	System	13 Aug 2020 00:56:53
User entered '97.2'	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6c10bcc6-53f6-44f4-b895-26914572dfbe'	System	13 Aug 2020 00:56:53
User entered 'No (N)'	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6c10bcc6-53f6-44f4-b895-26914572dfbe'	System	13 Aug 2020 00:56:53
User entered '12 Aug 2020 20:56'	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 6'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:06:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '65d67224-7306-45de-ac46-88a993d373c7'	System	14 Aug 2020 01:07:01
User entered 'Yes (Y)'	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:06:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '65d67224-7306-45de-ac46-88a993d373c7'	System	14 Aug 2020 01:07:01
User entered '99.1'	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:06:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '65d67224-7306-45de-ac46-88a993d373c7'	System	14 Aug 2020 01:07:01
User entered 'No (N)'	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:06:59', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '65d67224-7306-45de-ac46-88a993d373c7'	System	14 Aug 2020 01:07:01
User entered '13 Aug 2020 21:06'	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 7'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd58f0d20-7f6f-483a-8bd6-aa85f8cc92a7'	System	15 Aug 2020 01:22:25
User entered 'Yes (Y)'	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:14', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd58f0d20-7f6f-483a-8bd6-aa85f8cc92a7'	System	15 Aug 2020 01:22:25
User entered '99.5'	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:18', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd58f0d20-7f6f-483a-8bd6-aa85f8cc92a7'	System	15 Aug 2020 01:22:25
User entered 'No (N)'	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:21', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd58f0d20-7f6f-483a-8bd6-aa85f8cc92a7'	System	15 Aug 2020 01:22:25
User entered '14 Aug 2020 21:22'	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:14', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '44a1e9bc-eadb-48d6-8461-233dcefb29f2'	System	08 Aug 2020 18:30:39
User entered 'None (1)'	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:20', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '44a1e9bc-eadb-48d6-8461-233dcefb29f2'	System	08 Aug 2020 18:30:39
User entered 'No (N)'	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '44a1e9bc-eadb-48d6-8461-233dcefb29f2'	System	08 Aug 2020 18:30:39
User entered 'No (N)'	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '44a1e9bc-eadb-48d6-8461-233dcefb29f2'	System	08 Aug 2020 18:30:39
User entered 'None (1)'	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '44a1e9bc-eadb-48d6-8461-233dcefb29f2'	System	08 Aug 2020 18:30:39
User entered '08 Aug 2020 14:30'	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:58'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '52b8ebac-f57b-4fea-9c25-d9da83163a25'	System	09 Aug 2020 01:28:25
User entered 'None (1)'	System	09 Aug 2020 01:28:25

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '52b8ebac-f57b-4fea-9c25-d9da83163a25'	System	09 Aug 2020 01:28:25
User entered 'No (N)'	System	09 Aug 2020 01:28:25

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '52b8ebac-f57b-4fea-9c25-d9da83163a25'	System	09 Aug 2020 01:28:25
User entered 'No (N)'	System	09 Aug 2020 01:28:25

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:18', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '52b8ebac-f57b-4fea-9c25-d9da83163a25'	System	09 Aug 2020 01:28:25
User entered 'None (1)'	System	09 Aug 2020 01:28:25

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:22', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '52b8ebac-f57b-4fea-9c25-d9da83163a25'	System	09 Aug 2020 01:28:25
User entered '08 Aug 2020 21:28'	System	09 Aug 2020 01:28:25

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 17:53'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 2'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:30', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd7eaa078-ac14-43ad-9019-dd0926331fa4'	System	10 Aug 2020 00:37:53
User entered 'None (1)'	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd7eaa078-ac14-43ad-9019-dd0926331fa4'	System	10 Aug 2020 00:37:53
User entered 'No (N)'	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd7eaa078-ac14-43ad-9019-dd0926331fa4'	System	10 Aug 2020 00:37:53
User entered 'No (N)'	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd7eaa078-ac14-43ad-9019-dd0926331fa4'	System	10 Aug 2020 00:37:53
User entered 'None (1)'	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd7eaa078-ac14-43ad-9019-dd0926331fa4'	System	10 Aug 2020 00:37:53
User entered '09 Aug 2020 20:37'	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 3'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:23', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e42da60f-1cd4-4371-9a65-e4138f9716df'	System	11 Aug 2020 00:28:39
User entered 'None (1)'	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e42da60f-1cd4-4371-9a65-e4138f9716df'	System	11 Aug 2020 00:28:39
User entered 'No (N)'	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e42da60f-1cd4-4371-9a65-e4138f9716df'	System	11 Aug 2020 00:28:39
User entered 'No (N)'	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e42da60f-1cd4-4371-9a65-e4138f9716df'	System	11 Aug 2020 00:28:39
User entered 'None (1)'	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e42da60f-1cd4-4371-9a65-e4138f9716df'	System	11 Aug 2020 00:28:39
User entered '10 Aug 2020 20:28'	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 4'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:48:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3e429937-ab97-4006-aa1a-224dc04bf0eb'	System	11 Aug 2020 23:49:09
User entered 'None (1)'	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:48:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3e429937-ab97-4006-aa1a-224dc04bf0eb'	System	11 Aug 2020 23:49:09
User entered 'No (N)'	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:48:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3e429937-ab97-4006-aa1a-224dc04bf0eb'	System	11 Aug 2020 23:49:09
User entered 'No (N)'	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3e429937-ab97-4006-aa1a-224dc04bf0eb'	System	11 Aug 2020 23:49:09
User entered 'None (1)'	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:05', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3e429937-ab97-4006-aa1a-224dc04bf0eb'	System	11 Aug 2020 23:49:09
User entered '11 Aug 2020 19:49'	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 5'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0f39970d-4f5c-4e78-92d6-7d089e3d003f'	System	13 Aug 2020 00:56:24
User entered 'None (1)'	System	13 Aug 2020 00:56:24

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:11', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0f39970d-4f5c-4e78-92d6-7d089e3d003f'	System	13 Aug 2020 00:56:24
User entered 'No (N)'	System	13 Aug 2020 00:56:24

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0f39970d-4f5c-4e78-92d6-7d089e3d003f'	System	13 Aug 2020 00:56:24
User entered 'No (N)'	System	13 Aug 2020 00:56:24

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0f39970d-4f5c-4e78-92d6-7d089e3d003f' User entered 'None (1)'	System	13 Aug 2020 00:56:24
	System	13 Aug 2020 00:56:24

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:19', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0f39970d-4f5c-4e78-92d6-7d089e3d003f'	System	13 Aug 2020 00:56:24
User entered '12 Aug 2020 20:56'	System	13 Aug 2020 00:56:24

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 6'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dce340d7-9835-486d-ad23-e1f86f5f8bef'	System	14 Aug 2020 01:07:16
User entered 'None (1)'	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dce340d7-9835-486d-ad23-e1f86f5f8bef'	System	14 Aug 2020 01:07:16
User entered 'No (N)'	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dce340d7-9835-486d-ad23-e1f86f5f8bef'	System	14 Aug 2020 01:07:16
User entered 'No (N)'	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:12', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dce340d7-9835-486d-ad23-e1f86f5f8bef'	System	14 Aug 2020 01:07:16
User entered 'None (1)'	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dce340d7-9835-486d-ad23-e1f86f5f8bef'	System	14 Aug 2020 01:07:16
User entered '13 Aug 2020 21:07'	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 7'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b8c2d93b-ab5f-488b-a1ea-0ca9359c85e6'	System	15 Aug 2020 01:22:48
User entered 'None (1)'	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:38', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b8c2d93b-ab5f-488b-a1ea-0ca9359c85e6'	System	15 Aug 2020 01:22:48
User entered 'No (N)'	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b8c2d93b-ab5f-488b-a1ea-0ca9359c85e6'	System	15 Aug 2020 01:22:48
User entered 'No (N)'	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:43', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b8c2d93b-ab5f-488b-a1ea-0ca9359c85e6'	System	15 Aug 2020 01:22:48
User entered 'None (1)'	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b8c2d93b-ab5f-488b-a1ea-0ca9359c85e6'	System	15 Aug 2020 01:22:48
User entered '14 Aug 2020 21:22'	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:43', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e'	System	08 Aug 2020 18:31:05
User entered 'None (0)'	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e' User entered 'None (0)'	System	08 Aug 2020 18:31:05
	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:48', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e'	System	08 Aug 2020 18:31:05
User entered 'None (0)'	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e' User entered 'None (0)'	System	08 Aug 2020 18:31:05
	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e'	System	08 Aug 2020 18:31:05
User entered 'None (0)'	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:30:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e'	System	08 Aug 2020 18:31:05
User entered 'None (0)'	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:31:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e'	System	08 Aug 2020 18:31:05
User entered 'No (N)'	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T14:31:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '3f662c46-f1c3-4e87-9729-19b6c0dc648e' User entered '08 Aug 2020 14:31'	System	08 Aug 2020 18:31:05
	System	08 Aug 2020 18:31:05

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:58'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:27', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:30', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:39', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:41', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'None (0)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered 'No (N)'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-08T21:28:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0c91aba0-2fc7-46a2-a23d-a98c8903c547'	System	09 Aug 2020 01:28:52
User entered '08 Aug 2020 21:28'	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 17:53'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 2'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:37:59', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:05', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'None (0)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered 'No (N)'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-09T20:38:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c4b6891f-55c0-4ded-82ac-23e4d3ef240d'	System	10 Aug 2020 00:38:17
User entered '09 Aug 2020 20:38'	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 3'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:51', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:28:58', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:29:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:29:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:29:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'None (0)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:29:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered 'No (N)'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-10T20:29:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a1549c24-8313-4118-8179-604887e26516'	System	11 Aug 2020 00:29:18
User entered '10 Aug 2020 20:29'	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 4'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:26', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'None (0)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'None (0)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:49:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'None (0)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'None (0)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered 'No (N)'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-11T19:50:19', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4e5a658-bf07-4b19-af58-511b2d3ca920'	System	11 Aug 2020 23:50:23
User entered '11 Aug 2020 19:50'	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 5'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'None (0)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:38', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'None (0)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:44', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'None (0)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'None (0)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:55:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'None (0)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered 'No (N)'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-12T20:56:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a256e36e-b177-42d6-bfe3-0bf2d26fedf6'	System	13 Aug 2020 00:56:07
User entered '12 Aug 2020 20:56'	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 6'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'Some interference with activity (2)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:34', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'None (0)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'None (0)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'None (0)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:44', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'None (0)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered 'No (N)'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-13T21:07:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '51ab8897-3f07-408f-a1b0-f7f4efef6419'	System	14 Aug 2020 01:07:57
User entered '13 Aug 2020 21:07'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 7'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:22:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'None (0)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'None (0)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'None (0)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'None (0)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'None (0)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:12', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered 'No (N)'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-14T21:23:14', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd8aaf55b-2222-497c-aa3b-d356062cf0d2'	System	15 Aug 2020 01:23:16
User entered '14 Aug 2020 21:23'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 01:07:57
User entered 'Day 8'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-15T19:22:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7575b525-6ff7-47f3-a163-c45d734b7cb4'	System	15 Aug 2020 23:22:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-15T19:22:27', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7575b525-6ff7-47f3-a163-c45d734b7cb4'	System	15 Aug 2020 23:22:29
User entered '15 Aug 2020 19:22'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 01:23:16
User entered 'Day 9'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-16T20:56:47', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'bbe3451a-2e9a-45f6-a731-c8f8181cf719'	System	17 Aug 2020 00:56:51
User entered 'No interference with activity (1)'	System	17 Aug 2020 00:56:51

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-16T20:56:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'bbe3451a-2e9a-45f6-a731-c8f8181cf719'	System	17 Aug 2020 00:56:51
User entered '16 Aug 2020 20:56'	System	17 Aug 2020 00:56:51

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 23:22:29
User entered 'Day 10'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-17T16:47:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '112b0dfd-708a-416d-be31-f87a3cfbc63d'	System	17 Aug 2020 20:47:39
User entered 'None (0)'	System	17 Aug 2020 20:47:39

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-17T16:47:35', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '112b0dfd-708a-416d-be31-f87a3cfbc63d'	System	17 Aug 2020 20:47:39
User entered '17 Aug 2020 16:47'	System	17 Aug 2020 20:47:39

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 01:07:57
User entered 'Day 8'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-15T19:22:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b3790cf2-5b6c-4b53-acf2-152551d4dec0'	System	15 Aug 2020 23:22:41
User entered 'No (N)'	System	15 Aug 2020 23:22:41

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-15T19:22:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b3790cf2-5b6c-4b53-acf2-152551d4dec0'	System	15 Aug 2020 23:22:41
User entered '15 Aug 2020 19:22'	System	15 Aug 2020 23:22:41

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 01:23:16
User entered 'Day 9'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-16T20:56:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'eed8ec0c-5f1c-495d-af1f-2cbcb4a78c80'	System	17 Aug 2020 00:56:57
User entered 'No (N)'	System	17 Aug 2020 00:56:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-16T20:56:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'eed8ec0c-5f1c-495d-af1f-2cbcb4a78c80'	System	17 Aug 2020 00:56:57
User entered '16 Aug 2020 20:56'	System	17 Aug 2020 00:56:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 23:22:29
User entered 'Day 10'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-17T16:47:39', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '17aa84ce-f2bb-4f35-9030-517c0e44bc9d'	System	17 Aug 2020 20:47:46
User entered 'No (N)'	System	17 Aug 2020 20:47:46

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-08-17T16:47:41', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '17aa84ce-f2bb-4f35-9030-517c0e44bc9d'	System	17 Aug 2020 20:47:46
User entered '17 Aug 2020 16:47'	System	17 Aug 2020 20:47:46

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 23:22:29

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:12:02
	(b) (4)	

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered '16 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:12:02
	(b) (4)	

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 17:12:02
	(b) (4)	

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:12:02
	(b) (4)	

US3402299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:13

US3402299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 17:12:13

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:12:29
	(b) (4)	

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered '22 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:12:29
	(b) (4)	

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 17:12:29
	(b) (4)	

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:12:29
	(b) (4)	

US3402299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:53:51
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:12:37
	(b) (4)	

US3402299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 17:12:37

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:53:42

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:53:42

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	10 Sep 2020 15:53:42

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	10 Sep 2020 15:53:42
	(b) (4)	

US3402299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:53:48

US3402299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:53:48

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:03

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:03

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:03

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 15:56:03

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '11:08'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:08'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '98'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '62'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '12:12'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:10

US3402299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:10

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '11:41'	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:41'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	10 Sep 2020 15:56:22
	(b) (4)	

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:30

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:30

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '11:28'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:30

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:28'	System	10 Sep 2020 16:26:30

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:25'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:25'	System	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:26:51

US3402299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:26:51

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:13:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6aa3596b-7723-40a7-bff3-a09f8b97b20c'	System	10 Sep 2020 16:13:59
User entered 'Yes (Y)'	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:13:48', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6aa3596b-7723-40a7-bff3-a09f8b97b20c'	System	10 Sep 2020 16:13:59
User entered '98.1'	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:13:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6aa3596b-7723-40a7-bff3-a09f8b97b20c'	System	10 Sep 2020 16:13:59
User entered 'No (N)'	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:13:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6aa3596b-7723-40a7-bff3-a09f8b97b20c'	System	10 Sep 2020 16:13:59
User entered '10 Sep 2020 12:13'	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:24', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5ab9dc23-9b56-4109-8847-c7e013f7cd61'	System	11 Sep 2020 02:42:44
User entered 'Yes (Y)'	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5ab9dc23-9b56-4109-8847-c7e013f7cd61'	System	11 Sep 2020 02:42:44
User entered '98.2'	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:38', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5ab9dc23-9b56-4109-8847-c7e013f7cd61'	System	11 Sep 2020 02:42:44
User entered 'No (N)'	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5ab9dc23-9b56-4109-8847-c7e013f7cd61'	System	11 Sep 2020 02:42:44
User entered '10 Sep 2020 22:42'	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 2'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:59:09', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '641cb12b-6b7b-4b5f-93c4-0abe773037d8'	System	11 Sep 2020 23:59:26
User entered 'Yes (Y)'	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:59:16', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '641cb12b-6b7b-4b5f-93c4-0abe773037d8'	System	11 Sep 2020 23:59:26
User entered '97.6'	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:59:19', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '641cb12b-6b7b-4b5f-93c4-0abe773037d8'	System	11 Sep 2020 23:59:26
User entered 'No (N)'	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:59:21', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '641cb12b-6b7b-4b5f-93c4-0abe773037d8'	System	11 Sep 2020 23:59:26
User entered '11 Sep 2020 19:59'	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 3'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4cbca5ef-6960-48f2-83a4-5d3a3eb20eea' User entered 'Yes (Y)'	System	13 Sep 2020 01:38:38
	System	13 Sep 2020 01:38:38

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:30', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4cbca5ef-6960-48f2-83a4-5d3a3eb20eea' User entered '99.4'	System	13 Sep 2020 01:38:38
	System	13 Sep 2020 01:38:38

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:34', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4cbca5ef-6960-48f2-83a4-5d3a3eb20eea'	System	13 Sep 2020 01:38:38
User entered 'No (N)'	System	13 Sep 2020 01:38:38

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4cbca5ef-6960-48f2-83a4-5d3a3eb20eea'	System	13 Sep 2020 01:38:38
User entered '12 Sep 2020 21:38'	System	13 Sep 2020 01:38:38

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 4'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:40:56', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4816757-bb8c-4823-95f6-7b17920a6032'	System	14 Sep 2020 02:41:12
User entered 'Yes (Y)'	System	14 Sep 2020 02:41:12

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:02', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4816757-bb8c-4823-95f6-7b17920a6032'	System	14 Sep 2020 02:41:12
User entered '99.2'	System	14 Sep 2020 02:41:12

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:05', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4816757-bb8c-4823-95f6-7b17920a6032'	System	14 Sep 2020 02:41:12
User entered 'No (N)'	System	14 Sep 2020 02:41:12

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd4816757-bb8c-4823-95f6-7b17920a6032'	System	14 Sep 2020 02:41:12
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:12

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 5'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fd94f65-a728-4842-a613-84ba441f6738'	System	14 Sep 2020 23:42:10
User entered 'Yes (Y)'	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:42:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fd94f65-a728-4842-a613-84ba441f6738'	System	14 Sep 2020 23:42:10
User entered '96.8'	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:42:04', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fd94f65-a728-4842-a613-84ba441f6738'	System	14 Sep 2020 23:42:10
User entered 'No (N)'	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:42:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fd94f65-a728-4842-a613-84ba441f6738'	System	14 Sep 2020 23:42:10
User entered '14 Sep 2020 19:42'	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 6'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd6465ac1-4d7d-4cf2-850b-850d8faadf40'	System	16 Sep 2020 04:12:27
User entered 'Yes (Y)'	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:18', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd6465ac1-4d7d-4cf2-850b-850d8faadf40'	System	16 Sep 2020 04:12:27
User entered '97.8'	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:22', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd6465ac1-4d7d-4cf2-850b-850d8faadf40'	System	16 Sep 2020 04:12:27
User entered 'No (N)'	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:24', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'd6465ac1-4d7d-4cf2-850b-850d8faadf40'	System	16 Sep 2020 04:12:27
User entered '16 Sep 2020 00:12'	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 7'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:00:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e3dce245-02d8-4765-a381-74e50da38ada' User entered 'Yes (Y)'	System	17 Sep 2020 03:01:26
	System	17 Sep 2020 03:01:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:04', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e3dce245-02d8-4765-a381-74e50da38ada' User entered '98.2'	System	17 Sep 2020 03:01:26
	System	17 Sep 2020 03:01:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e3dce245-02d8-4765-a381-74e50da38ada'	System	17 Sep 2020 03:01:26
User entered 'No (N)'	System	17 Sep 2020 03:01:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:23', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e3dce245-02d8-4765-a381-74e50da38ada' User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:01:26
	System	17 Sep 2020 03:01:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '49cd1664-32a2-46cc-a592-aa793cb43d84'	System	10 Sep 2020 16:14:16
User entered 'None (1)'	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '49cd1664-32a2-46cc-a592-aa793cb43d84'	System	10 Sep 2020 16:14:16
User entered 'No (N)'	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '49cd1664-32a2-46cc-a592-aa793cb43d84'	System	10 Sep 2020 16:14:16
User entered 'No (N)'	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '49cd1664-32a2-46cc-a592-aa793cb43d84'	System	10 Sep 2020 16:14:16
User entered 'None (1)'	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '49cd1664-32a2-46cc-a592-aa793cb43d84'	System	10 Sep 2020 16:14:16
User entered '10 Sep 2020 12:14'	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:41:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dca1f21e-99e0-4236-b85e-93f352c75c17'	System	11 Sep 2020 02:41:59
User entered 'None (1)'	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:41:48', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dca1f21e-99e0-4236-b85e-93f352c75c17'	System	11 Sep 2020 02:41:59
User entered 'No (N)'	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:41:51', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dca1f21e-99e0-4236-b85e-93f352c75c17'	System	11 Sep 2020 02:41:59
User entered 'No (N)'	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:41:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dca1f21e-99e0-4236-b85e-93f352c75c17'	System	11 Sep 2020 02:41:59
User entered 'None (1)'	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:41:56', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dca1f21e-99e0-4236-b85e-93f352c75c17'	System	11 Sep 2020 02:41:59
User entered '10 Sep 2020 22:41'	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 2'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '253a440d-acc7-4f36-abc9-7baa2488352d'	System	11 Sep 2020 23:58:41
User entered 'None (1)'	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '253a440d-acc7-4f36-abc9-7baa2488352d'	System	11 Sep 2020 23:58:41
User entered 'No (N)'	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:35', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '253a440d-acc7-4f36-abc9-7baa2488352d' User entered 'No (N)'	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '253a440d-acc7-4f36-abc9-7baa2488352d'	System	11 Sep 2020 23:58:41
User entered 'None (1)'	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '253a440d-acc7-4f36-abc9-7baa2488352d' User entered '11 Sep 2020 19:58'	System	11 Sep 2020 23:58:41
	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 3'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '30b56313-265b-432c-9515-2cce088fba1b'	System	13 Sep 2020 01:37:51
User entered 'None (1)'	System	13 Sep 2020 01:37:51

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '30b56313-265b-432c-9515-2cce088fba1b' User entered 'No (N)'	System	13 Sep 2020 01:37:51
	System	13 Sep 2020 01:37:51

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:41', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '30b56313-265b-432c-9515-2cce088fba1b'	System	13 Sep 2020 01:37:51
User entered 'No (N)'	System	13 Sep 2020 01:37:51

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:44', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '30b56313-265b-432c-9515-2cce088fba1b' User entered 'None (1)'	System	13 Sep 2020 01:37:51
	System	13 Sep 2020 01:37:51

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:47', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '30b56313-265b-432c-9515-2cce088fba1b'	System	13 Sep 2020 01:37:51
User entered '12 Sep 2020 21:37'	System	13 Sep 2020 01:37:51

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 4'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:12', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c70a9c45-c38d-4d72-9883-7c01ce1c75ba'	System	14 Sep 2020 02:41:23
User entered 'None (1)'	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c70a9c45-c38d-4d72-9883-7c01ce1c75ba'	System	14 Sep 2020 02:41:23
User entered 'No (N)'	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c70a9c45-c38d-4d72-9883-7c01ce1c75ba'	System	14 Sep 2020 02:41:23
User entered 'No (N)'	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:19', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c70a9c45-c38d-4d72-9883-7c01ce1c75ba'	System	14 Sep 2020 02:41:23
User entered 'None (1)'	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:22', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c70a9c45-c38d-4d72-9883-7c01ce1c75ba'	System	14 Sep 2020 02:41:23
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 5'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:40:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8f72d19-7dd3-4881-9811-c46cb8497a0b'	System	14 Sep 2020 23:41:09
User entered 'None (1)'	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:40:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8f72d19-7dd3-4881-9811-c46cb8497a0b'	System	14 Sep 2020 23:41:09
User entered 'No (N)'	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8f72d19-7dd3-4881-9811-c46cb8497a0b'	System	14 Sep 2020 23:41:09
User entered 'No (N)'	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:04', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8f72d19-7dd3-4881-9811-c46cb8497a0b'	System	14 Sep 2020 23:41:09
User entered 'None (1)'	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:07', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8f72d19-7dd3-4881-9811-c46cb8497a0b'	System	14 Sep 2020 23:41:09
User entered '14 Sep 2020 19:41'	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 6'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:16', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b89566f9-3c7a-4093-9b55-3502997a4082'	System	16 Sep 2020 04:11:35
User entered 'None (1)'	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:21', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b89566f9-3c7a-4093-9b55-3502997a4082'	System	16 Sep 2020 04:11:35
User entered 'No (N)'	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b89566f9-3c7a-4093-9b55-3502997a4082'	System	16 Sep 2020 04:11:35
User entered 'No (N)'	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:28', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b89566f9-3c7a-4093-9b55-3502997a4082'	System	16 Sep 2020 04:11:35
User entered 'None (1)'	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b89566f9-3c7a-4093-9b55-3502997a4082'	System	16 Sep 2020 04:11:35
User entered '16 Sep 2020 00:11'	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 7'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c2f1ef16-9fbf-4bc7-a443-e4ac88b630cd'	System	17 Sep 2020 03:01:46
User entered 'None (1)'	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:36', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c2f1ef16-9fbf-4bc7-a443-e4ac88b630cd'	System	17 Sep 2020 03:01:46
User entered 'No (N)'	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c2f1ef16-9fbf-4bc7-a443-e4ac88b630cd' User entered 'No (N)'	System	17 Sep 2020 03:01:46
	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:39', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c2f1ef16-9fbf-4bc7-a443-e4ac88b630cd' User entered 'None (1)'	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:41', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c2f1ef16-9fbf-4bc7-a443-e4ac88b630cd'	System	17 Sep 2020 03:01:46
User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:19', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:21', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:26', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:28', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'None (0)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered 'No (N)'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T12:14:34', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e892cf60-ff9d-4ba6-9dfa-7f443e71c4ab'	System	10 Sep 2020 16:14:48
User entered '10 Sep 2020 12:14'	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:01', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:04', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'None (0)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered 'No (N)'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-10T22:42:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7a44d327-5c22-43ce-b666-998468bf745c'	System	11 Sep 2020 02:42:19
User entered '10 Sep 2020 22:42'	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 2'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:44', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:46', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:47', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'None (0)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:58:58', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered 'No (N)'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-11T19:59:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'e4828129-c2b0-468b-ad8a-63c6e178581b'	System	11 Sep 2020 23:59:03
User entered '11 Sep 2020 19:59'	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 3'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:51', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:56', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:37:58', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:02', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:06', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'None (0)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered 'No (N)'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-12T21:38:14', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '14468d0b-79f5-46f9-9fdc-b529cf291ee3'	System	13 Sep 2020 01:38:18
User entered '12 Sep 2020 21:38'	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 4'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:26', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:28', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:35', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'None (0)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered 'No (N)'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-13T22:41:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '79f36e97-42bf-4bdf-a6f8-a7f5ef50b214'	System	14 Sep 2020 02:41:45
User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 5'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:12', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:20', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:23', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:26', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'None (0)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered 'No (N)'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-14T19:41:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '08b12c17-895c-424d-aa82-090207432a23'	System	14 Sep 2020 23:41:35
User entered '14 Sep 2020 19:41'	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 6'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:42', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:51', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:56', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:11:58', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'None (0)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:02', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered 'No (N)'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T00:12:05', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '636ef7bd-bd47-419c-8574-227113c01576'	System	16 Sep 2020 04:12:07
User entered '16 Sep 2020 00:12'	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 15:56:22
User entered 'Day 7'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:45', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:47', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:48', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:52', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'None (0)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

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 (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered 'No (N)'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (880F1AC2-82DE-41AE-BCC6-35D06CF34ACA)', Time: '2020-09-16T23:01:59', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c75e69ef-f732-4187-a3c9-ee25c1701155'	System	17 Sep 2020 03:02:01
User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:56:22

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:56:22

US3402299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 18:55:46

US3402299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 18:55:46

US3402299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 18:55:46

US3402299

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 18:55:46

US3402299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 18:55:50

US3402299

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:55:50

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 14:57:35

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 14:57:35

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 14:57:35

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Sep 2020 14:57:35

US3402299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 14:57:24

US3402299

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 14:57:24

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:14:37

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:14:04
User entered '2 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 20:14:37

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:14:37

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:14:37

US3402299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:14:24

US3402299

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 20:14:24

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:18:54

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:18:54

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:18:54

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	15 Oct 2020 20:18:54

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '16:04'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 16:04'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 15:03:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORECT AS IS. NOT CLINICALLY SIGNIFICANT' (Site from System).	Traci Hull (b) (4)	15 Oct 2020 20:22:16
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Oct 2020 20:19:27
User entered '59'	Traci Hull (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:35

US3402299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:35

US3402299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:51

US3402299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:51

US3402299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '16:06'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:51

US3402299

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 16:06'	System	15 Oct 2020 20:22:51

US3402299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 20:22:56

US3402299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:22:56

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 71'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-16T12:46:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '88e4ac52-a4f8-445b-88a9-1253fbf4a3ac'	System	17 Oct 2020 14:10:31
User entered 'No (N)'	System	17 Oct 2020 14:10:31

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-16T12:47:03', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '88e4ac52-a4f8-445b-88a9-1253fbf4a3ac'	System	17 Oct 2020 14:10:31
User entered 'No (N)'	System	17 Oct 2020 14:10:31

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-16T12:47:08', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '88e4ac52-a4f8-445b-88a9-1253fbf4a3ac' User entered '16 Oct 2020 12:47:08'	System	17 Oct 2020 14:10:31
	System	17 Oct 2020 14:10:31

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 78'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-22T06:19:09', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '16a9162a-47e8-4964-8e10-7741a2530a8b' User entered 'No (N)'	System	22 Oct 2020 10:19:32
	System	22 Oct 2020 10:19:32

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-22T06:19:27', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '16a9162a-47e8-4964-8e10-7741a2530a8b' User entered 'No (N)'	System	22 Oct 2020 10:19:32
	System	22 Oct 2020 10:19:32

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-10-22T06:19:30', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '16a9162a-47e8-4964-8e10-7741a2530a8b' User entered '22 Oct 2020 06:19:30'	System	22 Oct 2020 10:19:32
	System	22 Oct 2020 10:19:32

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 92'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-05T16:14:26', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fbf6ea7-35d3-449f-872b-e3c51a4d6369'	System	05 Nov 2020 21:14:48
User entered 'No (N)'	System	05 Nov 2020 21:14:48

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-05T16:14:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fbf6ea7-35d3-449f-872b-e3c51a4d6369'	System	05 Nov 2020 21:14:48
User entered 'No (N)'	System	05 Nov 2020 21:14:48

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-05T16:14:46', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '6fbf6ea7-35d3-449f-872b-e3c51a4d6369'	System	05 Nov 2020 21:14:48
User entered '05 Nov 2020 16:14:46'	System	05 Nov 2020 21:14:48

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 99'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-14T15:00:58', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '90f48906-0014-4f57-afa6-51490c25392b'	System	14 Nov 2020 20:01:19
User entered 'No (N)'	System	14 Nov 2020 20:01:19

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-14T15:01:13', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '90f48906-0014-4f57-afa6-51490c25392b'	System	14 Nov 2020 20:01:19
User entered 'No (N)'	System	14 Nov 2020 20:01:19

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-14T15:01:17', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '90f48906-0014-4f57-afa6-51490c25392b' User entered '14 Nov 2020 15:01:17'	System	14 Nov 2020 20:01:19
	System	14 Nov 2020 20:01:19

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 18:24:04

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-23T00:01:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '623dcec6-0c29-4a47-aade-3ab7885727cf' User entered 'No (N)'	System	23 Nov 2020 05:02:05
	System	23 Nov 2020 05:02:05

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

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 (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-23T00:01:55', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '623dcec6-0c29-4a47-aade-3ab7885727cf'	System	23 Nov 2020 05:02:05
User entered 'No (N)'	System	23 Nov 2020 05:02:05

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2020-11-23T00:02:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '623dcec6-0c29-4a47-aade-3ab7885727cf' User entered '23 Nov 2020 00:02:00'	System	23 Nov 2020 05:02:05
	System	23 Nov 2020 05:02:05

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:39:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:39:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:39:57
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	06 Nov 2020 14:43:18

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '06 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:14:42
User entered '6 Nov 2020'	Tammy Kohn (b) (4)	06 Nov 2020 14:43:18

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	06 Nov 2020 14:43:18

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	06 Nov 2020 14:43:18

US3402299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	06 Nov 2020 14:43:26

US3402299

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:43:26

US3402299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User closed query 'Per EDC post dose 1 eDiary entry subject reported Headache with "Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity" extending beyond the 7 day period. Per protocol this needs to be recorded in AE Log in eCRF and source AE page and respective OTC medication needs to be recorded in source and eCRF ConMeds page. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:19:03
Query 'Per EDC post dose 1 eDiary entry subject reported Headache with "Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity" extending beyond the 7 day period. Per protocol this needs to be recorded in AE Log in eCRF and source AE page and respective OTC medication needs to be recorded in source and eCRF ConMeds page. Please update accordingly. ' answered with 'ADDED PER QUERY' (Site from CRA).	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:08:07
User opened query 'Per EDC post dose 1 eDiary entry subject reported Headache with "Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity" extending beyond the 7 day period. Per protocol this needs to be recorded in AE Log in eCRF and source AE page and respective OTC medication needs to be recorded in source and eCRF ConMeds page. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 00:48:09
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:29:06
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:06:14
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:20

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:36
User entered 'USA-US059-2020-mRNA-1273-P301000003'	System	04 Sep 2020 17:05:13
User entered 'New'	(b) (4), (b) (6)	04 Sep 2020 17:05:13

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haemorrhage, LLT: Postoperative bleeding - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:21:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:21:38
User closed query 'PV Query: Was the procedure for the abdominal pannus a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events or update event term to what caused the prolonged hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:32:13
User closed query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of Postoperative hypotension.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:32:07
User closed query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of postoperative bleeding. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:32:00
User closed query 'PV Query: Was the underlying reason for the panniculectomy considered as a AE/SAE, or was the reason for the procedure prior to consent. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:31:53
Query 'PV Query: Was the procedure for the abdominal pannus a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events or update event term to what caused the prolonged hospitalization. ' answered with 'term updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:28:55
Query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of Postoperative hypotension.' answered with 'changed term to post operative bleeding' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:28:37
Data point term sent to Coder	System	14 Sep 2020 01:28:26
Query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of postoperative bleeding. ' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:27:55

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Jennifer Molstead (b) (4)	14 Sep 2020 01:27:28
User entered 'Post Operative bleeding' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	14 Sep 2020 01:27:28
Query 'PV Query: Was the underlying reason for the panniculectomy considered as a AE/SAE, or was the reason for the procedure prior to consent. ' answered with 'it was there prior to consent, but the hospitalization was due to surgical complications' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:23:45
User opened query 'PV Query: Was the procedure for the abdominal pannus a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events or update event term to what caused the prolonged hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 20:12:57
User opened query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of Postoperative hypotension.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 20:12:26
User opened query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of postoperative bleeding. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 20:11:42
User opened query 'PV Query: Was the underlying reason for the panniculectomy considered as a AE/SAE, or was the reason for the procedure prior to consent. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 20:10:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms benign, HLT: Soft tissue neoplasms benign NEC, PT: Desmoid tumour, LLT: Abdominal fibromatosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:09:46
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 13:09:46
Data point term sent to Coder	System	03 Sep 2020 10:49:44
User entered 'ABDOMINAL PANNUS'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:48:55
Comment added 'AE HAPPENED BEFORE VISIT'.	Traci Hull (b) (4)	16 Sep 2020 16:15:28
User closed query 'PV Query: Please assess the event onset date (when the subject experienced the reason for the prolonged hospitalization).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:32:24
Query 'PV Query: Please assess the event onset date (when the subject experienced the reason for the prolonged hospitalization).' answered with 'correct as is' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:29:18
User opened query 'PV Query: Please assess the event onset date (when the subject experienced the reason for the prolonged hospitalization).' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 20:14:12
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	10 Sep 2020 15:56:22
User entered '26 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 01:27:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Sep 2020 01:27:28
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	14 Sep 2020 01:27:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 10:49:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Sep 2020 10:49:16
User entered 'UN:UN' (non-conformant).	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:27:28
User entered '26 Aug 2020 UN:UN' (non-conformant).	System	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '01 Sep 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 01:27:28
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	14 Sep 2020 01:27:28
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	03 Sep 2020 10:49:16
User entered '09:35'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:27:28
User entered '01 Sep 2020 09:35'	System	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '1'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '26 Aug 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '01 Sep 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '4'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '1'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Please check this box as Con Procedures were noted in source. ' answered with 'updated ' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:31:12
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:29:36
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	25 Nov 2020 03:29:36
User opened query 'Please check this box as Con Procedures were noted in source. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:36:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:10
User closed query 'Per EDC no Concomitant Procedure recorded - Please verify and update con Procedures page and Source if applicable. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:06:59
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:18:55
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:18:47
Query 'Per EDC no Concomitant Procedure recorded - Please verify and update con Procedures page and Source if applicable. ' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4)	24 Nov 2020 16:16:57
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:16:45
User entered '0' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 16:16:45
User opened query 'Per EDC no Concomitant Procedure recorded - Please verify and update con Procedures page and Source if applicable. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:47:24
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '1'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:18:32
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User closed query 'Per CDM, per previous DM CLR query, please record all Concomitant Medications given and Concomitant Procedures performed for POST OPERATIVE BLEEDING on corresponding eCRF pages, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:51:08
User closed query 'PV Query: Did the subject have their blood pressure taken and are any of those results available? If yes, please provide. If no, please confirm in your answer.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:12:24
User closed query 'PV Query: Are the reference ranges telling the normal values for hemoglobin and hematocrit available? If yes, please provide. If no, please confirm in your answer.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:12:21
User closed query 'PV Query: Since the subject had abdominal pannus prior to enrolling in the study, please consider adding abdominal pannus as medical history.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:12:17
Query 'PV Query: Are the reference ranges telling the normal values for hemoglobin and hematocrit available? If yes, please provide. If no, please confirm in your answer. ' answered with 'No ranges available' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 02 Oct 2020 17:23:48
Query 'Per CDM, per previous DM CLR query, please record all Concomitant Medications given and Concomitant Procedures performed for POST OPERATIVE BLEEDING on corresponding eCRF pages, otherwise explain.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 02 Oct 2020 17:05:37
Query 'PV Query: Did the subject have their blood pressure taken and are any of those results available? If yes, please provide. If no, please confirm in your answer.' answered with 'not that was provided' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 02 Oct 2020 17:05:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Since the subject had abdominal pannus prior to enrolling in the study, please consider adding abdominal pannus as medical history.'	Jennifer Molstead (b) (4)	02 Oct 2020 17:04:45
answered with 'Updated' (Site from Safety).		
User opened query 'Per CDM, per previous DM CLR query, please record all Concomitant Medications given and Concomitant Procedures performed for POST OPERATIVE BLEEDING on corresponding eCRF pages, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 13:08:56
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.	(b) (4), (b) (6)	02 Oct 2020 13:06:57
' (Site from DM).		
User opened query 'PV Query: Did the subject have their blood pressure taken and are any of those results available? If yes, please provide. If no, please confirm in your answer.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:08:02
User closed query 'PV Query: Please provide relevant specific blood pressure measurements with dates performed if available. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:08:02
User opened query 'PV Query: Are the reference ranges telling the normal values for hemoglobin and hematocrit available? If yes, please provide. If no, please confirm in your answer. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:07:53
User closed query 'PV Query: Please provide reference ranges and units for the hematocrit and hemoglobin results. If not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:07:53
User opened query 'PV Query: Since the subject had abdominal pannus prior to enrolling in the study, please consider adding abdominal pannus as medical history.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:07:42
User closed query 'PV Query: Please consider adding abdominal pannus as medical history. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:07:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' answered with 'CORRECT AS IS. PLEASE ADVISE ON QUERY RESOLUTION' (Site from DM).	Traci Hull (b) (4) (b) (4)	23 Sep 2020 18:26:11
Query 'PV Query: Please provide reference ranges and units for the hematocrit and hemoglobin results. If not available please state so. ' answered with 'CORRECT AS IS. PLEASE ADVISE ON QUERY RESOLUTION' (Site from Safety).	Traci Hull (b) (4) (b) (4)	23 Sep 2020 18:26:03
Query 'PV Query: Please consider adding abdominal pannus as medical history. ' answered with 'CORRECT AS IS. PLEASE ADVISE ON QUERY RESOLUTION' (Site from Safety).	Traci Hull (b) (4) (b) (4)	23 Sep 2020 18:25:55
Query 'PV Query: Please provide relevant specific blood pressure measurements with dates performed if available. ' answered with 'CORRECT AS IS. PLEASE ADVISE ON QUERY RESOLUTION' (Site from Safety).	Traci Hull (b) (4) (b) (4)	23 Sep 2020 18:25:34
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 07:07:05
User opened query 'PV Query: Please provide reference ranges and units for the hematocrit and hemoglobin results. If not available please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 20:13:18
User opened query 'PV Query: Please consider adding abdominal pannus as medical history. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 20:11:56
User opened query 'PV Query: Please provide relevant specific blood pressure measurements with dates performed if available. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 20:11:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject went in hospital for routine panniculectomy. After the procedure the patients hospital course was complicated by hypotension. She received 2.5L of fluid. A "Rapid Response was called on 27Aug2020 for patients hypotension. Patient was taken back to the OR for a possible post operative bleed. 2-3 small atreial perforations were cauterized on rectus fascia, and a small amount of oozing from surrounding muscle was seen. The patient received 2 units of Packed Red Blood Cells. intraoperatively. Patient remained hypotensive, and was given an additional 2 units pf Packed Red Blood Cells. she was then transferred to ICU and given an additional fluid bolus. Subjects Hemaglobin and Hematocrit went from 10.0/31.1L 27Aug2020 at 07:18 to 7.7/23.5 27Aug2020 at 11:26 to 9.1/28.2L 28/Aug at 04:22. Subject also had CT of the abdomen and pelvis which was relatively normal. Subject also had a CT Angiography of the chest to rule out pulmonary embolism. No Pulminary Emboli were found. Chest X-Ray 29Aug2020 Normal. Abdominal X-Ray Normal. After significant recovery patient was discharged 01Sep2020.'	Jennifer Molstead (b) (4)	(b) (4) 03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 00:09:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 00:09:50
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 00:08:13
User entered 'SEVERE HEADACHE'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Yes (Y)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '11 Aug 2020'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '16 Aug 2020'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Related (RELATED)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Not Related (NOT RELATED)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'None (NONE)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '1'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4)	10 Nov 2020 00:07:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 00:07:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:33:07
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 21:49:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 21:49:51
Data point term sent to Coder	System	08 Aug 2020 21:49:02
User entered 'TRAZADONE'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'INSOMNIA'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '150'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:48:59
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 21:50:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 21:48:59
User entered 'UN UNK 2016'	Traci Hull (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:50:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 21:50:51
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 21:50:51
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:48:59
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 21:48:59

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:07:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:07:17
Data point term sent to Coder	System	08 Aug 2020 21:50:02
User entered 'LACTULOSE'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'CONSTIPATION'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '10'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'g (g)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:49:31
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 21:50:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 21:49:31
User entered 'UN UNK 2010'	Traci Hull (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:49:31
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:50:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 21:50:38
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 21:50:38
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:49:31
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 21:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 21:51:51
Data point term sent to Coder	System	08 Aug 2020 21:51:03
User entered 'LEVOTHYROXINE'	Traci Hull (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'HYPOTHYROIDISM'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '50'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'ug (ug)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 21:50:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 21:50:05
User entered 'UN UNK 2008'	Traci Hull (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:50:05
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 21:50:05

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:05:14
Data point term sent to Coder	System	10 Aug 2020 13:09:13
User entered 'SUMITRIPTAN (IMITREX)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'MIGRAINES'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '50'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:14:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:08:44
User entered 'UN UNK 2016'	Traci Hull (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 13:08:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:11:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:11:13
Data point term sent to Coder	System	10 Aug 2020 13:10:14
User entered 'DULOXETINE'	Traci Hull (b) (4)	10 Aug 2020 13:09:20
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'DEPRESSION'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '40'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:14:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:09:20
User entered 'UN UNK 2018'	Traci Hull (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:12:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:12:16
Data point term sent to Coder	System	10 Aug 2020 13:11:17
User entered 'clonazepam'	Traci Hull (b) (4)	10 Aug 2020 13:10:44
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'ANXIETY/DEPRESSION'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0.5'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:13:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:10:44
User entered 'UN UNK 2018'	Traci Hull (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:10:44

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 13:12:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 13:12:15
Data point term sent to Coder	System	10 Aug 2020 13:11:18
User entered 'MULTIVITAMIN'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'NUTRITIONAL SUPPLEMENT'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '1'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'tablet (TABLET)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:13:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:11:17
User entered 'UN UNK 2010'	Traci Hull (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:11:17

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 13:47:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 13:47:13
Data point term sent to Coder	System	10 Aug 2020 13:13:21
User entered 'VITAMIN B12'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'NUTRITIONAL SUPPLEMENT'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '1000'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'ug (ug)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'every month (QM)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:13:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:12:46
User entered 'UN UNK 2010'	Traci Hull (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '802 (802)'	System	10 Aug 2020 13:12:46

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LUBIPROSTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:50:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:50:22
Data point term sent to Coder	System	10 Aug 2020 13:14:22
User entered 'lubiprostone'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'CONSTITPATION'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '24'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'ug (ug)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	10 Aug 2020 13:13:28
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 13:13:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:13:28
User entered 'UN UNK 2011'	Traci Hull (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:13:28

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE HEADACHES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:26:44
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE HEADACHES should be recorded, and update con med indication or provide clarification. ' answered with 'NO WORSENING OF MIGRAINE HEADACHES. PATIENT HAD ISSUES PRIOR TO BEGINNING OF STUDY.' (Site from DM).	Tammy Kohn (b) (4)	18 Nov 2020 19:24:16
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE HEADACHES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:20:36
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 17:15:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 17:15:35
Data point term sent to Coder	System	24 Aug 2020 17:14:47
User entered 'IBUPROFEN'	Traci Hull (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'MIGRAINE HEADACHES'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '400'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '12 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 16:54:04
User entered '14 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '15 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 17:14:25

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: METOCLOPRAMIDE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 14:56:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 14:56:54
Data point term sent to Coder	System	18 Sep 2020 14:55:48
Data point term sent to Coder	System	18 Sep 2020 14:54:47
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 14:54:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: METOCLOPRAMIDE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:13:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:13:22
Data point term sent to Coder	System	03 Sep 2020 10:53:44
User entered 'Metoclopramide HCL'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please consider updating Indication in this medication and others related according to updated SAE Term, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:20:10
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
Query 'Per ETRTR: Please consider updating Indication in this medication and others related according to updated SAE Term, thanks.' answered with 'DATA UPDATED NOT RELATED TO SAE' (Site from CRA).	Tammy Kohn (b) (4)	18 Sep 2020 14:55:28
User entered 'PANNUS OF ABDOMINAL AREA' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 14:55:03
User entered 'PANNUS' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 14:54:31
User opened query 'Per ETRTR: Please consider updating Indication in this medication and others related according to updated SAE Term, thanks.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 21:44:06
User entered 'Abdominal Pannus'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '10'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '26 Aug 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '01 Sep 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:53:09
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 06:53:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 06:53:32
Data point term sent to Coder	System	12 Oct 2020 17:53:04
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 17:52:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:14:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 11:14:33
Data point term sent to Coder	System	03 Sep 2020 10:54:45
User entered 'Ondansetron'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:08:15
User closed query 'Thank you for your response. However, the entry added to MH is 'ABNORMAL PANNUS'. Please review indication/condition and reconcile. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:04:03
Query 'Thank you for your response. However, the entry added to MH is 'ABNORMAL PANNUS'. Please review indication/condition and reconcile. ' answered with 'IDIOPATHIC ABDOMINAL PANNUS Without Rheumatoid Arthritis or Trauma' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 17:55:28
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 17:52:40
User entered 'IDIOPATHIC ABDOMINAL PANNUS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 17:52:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User opened query 'Thank you for your response. However, the entry added to MH is 'ABNORMAL PANNUS'. Please review indication/condition and reconcile. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:46:12
User closed query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:46:12
Query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF. ' answered with 'DATA UPDATED ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 16:56:15
User opened query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 04:44:40
User entered 'Abdominal Pannus'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '4'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '10 Nov 2010' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 16:55:26
User entered '26 Aug 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '01 Sep 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this is appropriately recorded in this field or this should be moved to a more appropriate field. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:32:23
Query 'Per DM CLR: Please review if this is appropriately recorded in this field or this should be moved to a more appropriate field. Update as appropriate. Otherwise, provide clarification. ' answered with 'THIS IS RECORDED IN THE APPROPRIATE FIELD AS THIS WAS GIVING AS A MED TO TREAT THE PATIENT.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 19:55:52
User opened query 'Per DM CLR: Please review if this is appropriately recorded in this field or this should be moved to a more appropriate field. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:21:36
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #13 (Has received systemic immunoglobulins or blood products within 3 months prior to the date of screening' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:27:38
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #13 (Has received systemic immunoglobulins or blood products within 3 months prior to the date of screening' answered with 'THIS HAS BEEN REPORTED AS A PROTOCOL DEVIATION' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Nov 2020 21:04:33
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #13 (Has received systemic immunoglobulins or blood products within 3 months prior to the date of screening' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:19:01
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:13:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:13:44
Data point term sent to Coder Coding entries removed.	System Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 17:07:53 02 Oct 2020 17:06:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:07:38
Data point term sent to Coder User entered '4 units Packed Red Blood Cells'	System Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:57:45 03 Sep 2020 10:57:36

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Post operative bleeding' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	02 Oct 2020 17:06:58
User entered 'Abdominal Pannus'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '1000'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mL (mL)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '28 Aug 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '29 Aug 2020'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:57:36

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:57:36

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 10:57:36

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:03:51
Data point term sent to Coder	System	02 Oct 2020 13:23:03
User entered 'Influenza vaccination'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Prophylaxis for influenza'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0.5'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mL (mL)'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once (ONCE)'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '29 Sep 2020'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '29 Sep 2020'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Abigail Wine (b) (4)	02 Oct 2020 13:23:01
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 13:23:01

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:57:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:57:47
Data point term sent to Coder User entered 'ibuprofen'	System Tarin Gordon (b) (4) (b) (4)	12 Nov 2020 14:56:11 12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'No (N)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'headache'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered '400'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'mg (mg)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered empty.	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered empty.	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered empty.	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered '14 Aug 2020'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered '0'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'No (N)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered '15 Aug 2020'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:24:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	12 Nov 2020 14:55:35
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:35:48
User opened query 'Please add Con Procedures to EDC Con procedures log. Per Source - - Panniculectomy (Planned) - 26 Aug 2020. - CBC (Post Op bleeding) - 27 Aug 2020 - CT Angiography (Post Op Bleeding) - 27 Aug 2020 - CT Abdomen (Post Op Bleeding) - 27 Aug 2020 - CT Pelvis (Post Op Bleeding) - 27 Aug 2020 - CXR (Post Op Bleeding) - 27 Aug 2020 - CBC (Post Op Bleeding) - 28 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:35:14
DataPoint Un-verified.	Jennifer Molstead (b) (4)	24 Nov 2020 17:15:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	24 Nov 2020 17:15:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 00:50:35
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 21:50:58
	(b) (4)	

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'USA-US059-2020-MRNA-1273-P301000003'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:38:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:03:08
User entered 'US' (non-conformant).	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Oct 2020 14:13:15
User entered '2'	System	14 Sep 2020 20:03:54
User entered '1'	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'USA-US059-2020-MRNA-1273-P301000003'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:38:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:03:08
User entered 'US' (non-conformant).	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Oct 2020 14:13:15
User entered '2'	System	14 Sep 2020 20:03:54
User entered '1'	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
User entered '04/Sep/2020 13:07'	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:40

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)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:03:08
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'USA-US059-2020-MRNA-1273-P301000003'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:38:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:03:08
User entered 'US' (non-conformant).	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Oct 2020 14:13:15
User entered '2'	System	14 Sep 2020 20:03:54
User entered '1'	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
User entered '14/Sep/2020 16:03'	System	14 Sep 2020 20:03:54

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:40

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)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 20:03:54

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'USA-US059-2020-MRNA-1273-P301000003'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	04 Sep 2020 17:06:58
User entered 'No (N)'	System	04 Sep 2020 17:05:13

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:12:45
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:47:14

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:38:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:03:08
User entered 'US' (non-conformant).	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Oct 2020 14:13:15
User entered '2'	System	14 Sep 2020 20:03:54
User entered '1'	System	04 Sep 2020 17:07:04

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
User entered '05/Oct/2020 14:13'	System	05 Oct 2020 14:13:15

US3402299

Folder: SAE USA-US059-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:40

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)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 14:13:15