

US3402299 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402299

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

[Participant ID](#)

US3402299

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

US3402299

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:49:57

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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 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:49:57

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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 <input type="radio"/> No <input checked="" type="radio"/>
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)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN JUL 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	CHRONIC CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	ALLERGY TO AMOXYCILLAN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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 <input type="radio"/> No <input checked="" type="radio"/>
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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:49:57

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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

Data signed: (b) (4) 15 Feb 2021 17:49:57

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Date of assessment (dd MMM yyyy) 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 (dd MMM yyyy) UN UNK 2003

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:49:57

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

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US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

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US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

TIMEPOINT

DAY 9

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 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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

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US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:27:25

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:49:56

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:25:29

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 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

Data signed: (b) (4) 15 Feb 2021 17:49:57

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	16:06 (24 HR)
Collection date and time (derived)	15 OCT 2020 16:06

US3402299

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:17

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 06:15:53
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: 09 Jun 2021 17:27:25

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

Date and time of submission

10 DEC 2020 20:01:00

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: 09 Jun 2021 17:27:25

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

Date and time of submission

16 DEC 2020 13:53:28

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: 09 Jun 2021 17:27:25

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

Date and time of submission

21 DEC 2020 06:00:33

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: 09 Jun 2021 17:27:25

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

Date and time of submission

28 DEC 2020 07:27:39

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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 20:21:15
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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 06:00:37
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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 07:19:40
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: 09 Jun 2021 17:27:25

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

Date and time of submission

25 JAN 2021 12:41:21

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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 15:10:05
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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 22:19:50
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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 06:18:54
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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 06:15:33
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: 09 Jun 2021 17:27:25

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

Date and time of submission

01 MAR 2021 06:17:49

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: 09 Jun 2021 17:27:25

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

Date and time of submission

08 MAR 2021 17:19:16

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: 09 Jun 2021 17:27:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 07:30:56
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: 09 Jun 2021 17:27:25

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

Date and time of submission

22 MAR 2021 06:15:46

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: 09 Jun 2021 17:27:25

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

Date and time of submission

29 MAR 2021 08:22:41

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: 09 Jun 2021 17:27:25

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

Date and time of submission

05 APR 2021 20:14:55

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: 09 Jun 2021 17:27:25

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

Date and time of submission

12 APR 2021 06:06:39

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: 09 Jun 2021 17:27:25

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

Date and time of submission

19 APR 2021 18:19:37

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: 09 Jun 2021 17:27:25

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

Date and time of submission

27 APR 2021 07:07:10

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: 09 Jun 2021 17:27:25

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

Date and time of submission

03 MAY 2021 19:54:23

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

Patient Cloud Open Date & Time	16 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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°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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Date and time of submission	
Patient Cloud Open Date & Time	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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 NOV 2021 00:01
Patient Cloud Close Date & Time	19 NOV 2021 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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°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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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°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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2022 00:01
Patient Cloud Close Date & Time	01 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

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

Date and time of submission	
Patient Cloud Open Date & Time	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: 09 Jun 2021 17:27:25

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°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: 09 Jun 2021 17:27:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3402299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:27:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 23:08:57

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:25:29

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 08 Mar 2021 22:25:29

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	11 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 MAR 2021
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Collection time (00:00-23:59)	15:05 (24 HR)
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Collection date and time (derived)	11 MAR 2021 15:05
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US3402299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402299

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:27:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:37
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:32
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

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

Treatment Date and Time (derived) 14 JAN 2021 15:00

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	14:29 (24 HR)
Collection date and time (derived)	14 JAN 2021 14:29

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:26
Collection Date and Time (derived)	14 JAN 2021 14:26

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402299

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3402299

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:24
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3402299

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3402299

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 14:57

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:26

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Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

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 OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 09 Jun 2021 17:27:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	15:05 (24 HR)
Collection date and time (derived)	11 MAR 2021 15:05

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

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)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

AEID	USA-US059-2020-MRNA-1273-P30 1000003
Adverse event	POST OPERATIVE BLEEDING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	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 <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

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.

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)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Mar 2021 14:44:39

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AFTER INJECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 AUG 2020	PANNICULECTOMY	Other	PLANNED PROCEDURE
27 AUG 2020	COMPLETE BLOOD COUNT	Adverse Event	
27 AUG 2020	CT ANGIOGRAPHY	Adverse Event	
27 AUG 2020	CT ABDOMEN	Adverse Event	
27 AUG 2020	CT PELVIS	Adverse Event	
27 AUG 2020	CHEST XRAY	Adverse Event	
28 AUG 2020	POST OPERATIVE BLEEDING	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:27:25

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

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6

US3402299

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

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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

US3402299

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

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:46
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 (5)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	07/DEC/2020 09:49
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 (6)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 09 Jun 2021 17:27:25

SAEID	USA-US059-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:46
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: 09 Jun 2021 17:27:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:55:26
User entered 'US3402299'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:35:25

US3402299

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'SCRN'	System	08 Aug 2020 18:23:11

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 17:35:27

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '50'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'YEARS'	System	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '50'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered 'Female (F)'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
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: 09 Jun 2021 17:27:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered 'l'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 18:23:20

US3402299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:25

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:20
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:59:16
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:59:16
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Aug 2020'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2020'	System	08 Aug 2020 18:23:31

US3402299

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'I'	System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:35:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:39:19

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Nov 2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Nov 2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2010'	System	08 Aug 2020 21:40:21

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:44
Data point term sent to Coder	System	15 Feb 2021 17:49:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Aug 2020 21:41:50
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 1990'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 1990'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jul 1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jul 1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '1990'	System	08 Aug 2020 21:40:52

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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) (b) (4)	15 Feb 2021 17:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 17:50:44
Data point term sent to Coder	System	15 Feb 2021 17:49:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:49:57
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) (b) (4)	08 Aug 2020 21:42:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 21:42:50
Data point term sent to Coder	System	08 Aug 2020 21:41:57
User entered 'CHRONIC CONSTIPATION'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2010'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2010'	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2010'	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:06

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:01
Data point term sent to Coder	System	15 Feb 2021 17:49:57
User signature succeeded.	Frank Eder (b) (4)	
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Aug 2020 21:42:50
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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2000'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:19

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2000'	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2000'	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:19

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:45
Data point term sent to Coder	System	15 Feb 2021 17:50:01
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Aug 2020 21:42:50
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)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2008'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:34

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2008'	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2008'	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:34

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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) (b) (4)	15 Feb 2021 17:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 17:50:40
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:49:57
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) (b) (4)	08 Aug 2020 21:42:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 21:42:50
Data point term sent to Coder	System	08 Aug 2020 21:41:58
User entered 'MIGRAINE'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 1988'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 1988'	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '1988'	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:41:48

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:39
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Aug 2020 21:43:50
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2018'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2018'	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2018'	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:02

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:41
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Aug 2020 21:43:50
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2018'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:13

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2018'	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2018'	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:13

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	15 Feb 2021 17:50:41
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	11 Aug 2020 21:58:26
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
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	11 Aug 2020 14:04:08
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
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	10 Aug 2020 16:26:15
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 1990'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 1990'	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '1990'	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:42:35

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:40
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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)	30 Oct 2020 14:44:35
	(b) (4)	
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

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
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)	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)	
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.	(b) (4), (b) (6)	08 Oct 2020 04:30:55
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: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:40
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2003'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN UNK 2003' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 14:11:22
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jan 2003'	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2003'	System	08 Aug 2020 21:42:51

US3402299

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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) (b) (4)	15 Feb 2021 17:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 17:50:46
Data point term sent to Coder	System	15 Feb 2021 17:50:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:49:57
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) (b) (4)	08 Aug 2020 21:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 21:44:50
Data point term sent to Coder	System	08 Aug 2020 21:44:00
User entered 'RIGHT WRIST FRACTURE'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'UN Jul 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Jul 2020'	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2020'	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered empty.	System	08 Aug 2020 21:43:12

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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)	15 Feb 2021 17:50:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	15 Feb 2021 17:50:43
Data point term sent to Coder	System	15 Feb 2021 17:50:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4)	09 Nov 2020 00:41:30
	(b) (4), (b) (6)	
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
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	22 Oct 2020 14:51:40
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
Coding entries removed.	(b) (4)	21 Oct 2020 16:30:03
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)	

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

Condition

Audit	User	Time (GMT)
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
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
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
Data point term sent to Coder	System	08 Oct 2020 14:33:52
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)	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)	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)	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)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '10 Nov 2010'	Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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
DataPoint Un-verified.	(b) (4) Tammy Kohn (b) (4)	09 Nov 2020 22:53:11
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	09 Nov 2020 22:53:11
DataPoint Verified.	(b) (4) (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
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	05 Oct 2020 16:14:20
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4) Jennifer Molstead (b) (4)	02 Oct 2020 17:18:54
User entered '02 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:41:30
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered 'Nov 2010'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2010'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User entered '2020'	System	02 Oct 2020 17:18:41

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:01:45
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:00:00
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:00:00
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

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered '13:00'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:53

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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
DataPoint set to visible.	(b) (4) System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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
DataPoint set to visible.	(b) (4) System	08 Aug 2020 18:23:34

US3402299

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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).	(b) (4), (b) (6)	12 Oct 2020 09:55:39
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).	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:21:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:20:55
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)	09 Oct 2020 11:56:53
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 11:56:51
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) (b) (4)	08 Oct 2020 21:06:31
User entered '37.1' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 21:06:24

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
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)	06 Oct 2020 14:46:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:46:44
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

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:21:03
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) (b) (4)	08 Oct 2020 21:06:36
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) (b) (4)	02 Oct 2020 17:41:39
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:24
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:43:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (b) (4)	09 Oct 2020 13:21:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (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) (b) (4)	02 Oct 2020 17:41:19

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[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
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (b) (4), (b) (6)	06 Oct 2020 14:46:35
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:16
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 entered '18'	(b) (4) Traci Hull (b) (4)	08 Aug 2020 21:43:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (b) (4), (b) (6)	06 Oct 2020 14:46:37
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:21
User opened query 'Data is required. Please provide.' System (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 entered '100'	(b) (4) Traci Hull (b) (4)	08 Aug 2020 21:43:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (b) (4), (b) (6)	06 Oct 2020 14:46:38
Query 'Data is required. Please provide.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	02 Oct 2020 17:41:24
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	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 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) (4), (b) (6)	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).	Traci Hull (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).	(b) (4) System	16 Sep 2020 23:48:56
User entered '58'	Traci Hull (b) (4)	08 Aug 2020 21:43:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
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

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:40
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:12

US3402299

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (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).	System	10 Sep 2020 15:56:03
User entered '8 Aug 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:12

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:03:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:00:16
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) (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

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'Surgically sterile (SURGICALLY STERILE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered 'UN UNK 2003'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:27:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:42:53
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:44:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4) Traci Hull (b) (4)	08 Aug 2020 21:45:12

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered 'I'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

US3402299

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered '0'	(b) (4) Traci Hull (b) (4)	08 Aug 2020 21:45:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:40
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:08
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:12

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:18
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:25

US3402299

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 05:07:30
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:20
User entered '08 Aug 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 13:01:20
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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:18
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:25

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'VISIT1'	System	08 Aug 2020 21:45:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:36

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:36

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:43:57
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:45:36

US3402299

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:25

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
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)	
User entered '160.2' cm	(b) (4), (b) (6)	24 Sep 2020 17:44:46
	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: 09 Jun 2021 17:27:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User closed query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	(b) (4)	
Query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' answered with 'DATA UPDATED TO ND' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:53:29
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
DataPoint Verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 11:11:38
User entered '77.2' kg	(b) (4), (b) (6)	09 Nov 2020 00:44:05
	(b) (4)	
	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
	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: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
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)	
User entered '160.2' cm	(b) (4), (b) (6)	24 Sep 2020 17:44:46
	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: 09 Jun 2021 17:27:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User closed query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	(b) (4)	
Query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' answered with 'DATA UPDATED TO ND' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:53:29
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
DataPoint Verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 11:11:38
User entered '77.2' kg	(b) (4), (b) (6)	09 Nov 2020 00:44:05
	(b) (4)	
	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
	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: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Yes (Y)'	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: 09 Jun 2021 17:27:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:44
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:44
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '13:20'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '37.1' C	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '66'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'bpm'	System	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '18'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'breaths/min'	System	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '100'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

Height

Audit	User	Time (GMT)
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)	
User entered '160.2' cm	(b) (4), (b) (6)	24 Sep 2020 17:44:46
	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: 09 Jun 2021 17:27:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User closed query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	(b) (4)	
Query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' answered with 'DATA UPDATED TO ND' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:53:29
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Dec 2020 13:46:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please enter "ND-NOT DONE" in the data field of EDC for Height and Weight (without unit)' (Site from DM).	Tammy Kohn (b) (4)	19 Dec 2020 13:46:51
DataPoint Verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 11:11:38
User entered '77.2' kg	(b) (4), (b) (6)	09 Nov 2020 00:44:05
	(b) (4)	
	Tammy Kohn (b) (4)	02 Oct 2020 17:42:15
	(b) (4)	
	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User accepted default value 'Post-Dose (POSTDOSE)'	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Yes (Y)'	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 (2)

Generated On: 09 Jun 2021 17:27:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:38
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:44
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:01:44
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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) (b) (4)	08 Aug 2020 21:47:14
User opened 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).		08 Aug 2020 21:47:04
User entered '14:39'	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 (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '36.8' C	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered 'Oral (Oral)'	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 (2)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered empty.	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: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '58'	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'bpm'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '16'	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'breaths/min'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '106'	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 (2)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	08 Aug 2020 21:47:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:47
User entered '76'	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 (2)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	08 Aug 2020 21:47:04

US3402299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:26

US3402299

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:44:52
User entered empty; reason for change Data Entry Error	Traci Hull (b) (4) (b) (4)	10 Sep 2020 16:27:26
User entered '8 Aug 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:26

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:02
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 18:24:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:53:15
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:01:58
User entered '08 Aug 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 13:01:58
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 18:24:04

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:42

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:54:43
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:02:09
User entered '08 Aug 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 13:02:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered '8 Aug 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:42

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:09
User entered '13:59'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:47:42

US3402299

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:54:47
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 13:02:21
User entered '08 Aug 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 13:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered '8 Aug 2020'	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: 09 Jun 2021 17:27:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered 'Yes (Y)'	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: 09 Jun 2021 17:27:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered '13:56'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered 'No (N)'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:15
User entered empty.	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered empty.	System	08 Aug 2020 21:48:06

US3402299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:45:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 21:48:12

US3402299

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	08 Aug 2020 21:48:12

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	08 Aug 2020 18:30:06
	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '98.2'	System	08 Aug 2020 18:30:06
	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '08 Aug 2020 14:30'	System	08 Aug 2020 18:30:06
	System	08 Aug 2020 18:30:06

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	09 Aug 2020 01:28:02
	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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
	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	09 Aug 2020 01:28:02
	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '08 Aug 2020 21:28'	System	09 Aug 2020 01:28:02
	System	09 Aug 2020 01:28:02

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	10 Aug 2020 00:38:56
	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '97.6'	System	10 Aug 2020 00:38:56
	System	10 Aug 2020 00:38:56

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	11 Aug 2020 00:28:16
	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '97.9'	System	11 Aug 2020 00:28:16
	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Aug 2020 00:28:16
	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Aug 2020 20:28'	System	11 Aug 2020 00:28:16
	System	11 Aug 2020 00:28:16

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	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: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	13 Aug 2020 00:56:53
	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '97.2'	System	13 Aug 2020 00:56:53
	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Aug 2020 20:56'	System	13 Aug 2020 00:56:53
	System	13 Aug 2020 00:56:53

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	14 Aug 2020 01:07:01
	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '99.1'	System	14 Aug 2020 01:07:01
	System	14 Aug 2020 01:07:01

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	15 Aug 2020 01:22:25
	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '99.5'	System	15 Aug 2020 01:22:25
	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	15 Aug 2020 01:22:25
	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '14 Aug 2020 21:22'	System	15 Aug 2020 01:22:25
	System	15 Aug 2020 01:22:25

US3402299

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	08 Aug 2020 18:30:39
	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	08 Aug 2020 18:30:39
	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '08 Aug 2020 14:30'	System	08 Aug 2020 18:30:39
	System	08 Aug 2020 18:30:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	10 Aug 2020 00:37:53
	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '09 Aug 2020 20:37'	System	10 Aug 2020 00:37:53
	System	10 Aug 2020 00:37:53

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	11 Aug 2020 00:28:39
	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Aug 2020 00:28:39
	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Aug 2020 00:28:39
	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	11 Aug 2020 00:28:39
	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Aug 2020 20:28'	System	11 Aug 2020 00:28:39
	System	11 Aug 2020 00:28:39

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	11 Aug 2020 23:49:09
	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Aug 2020 23:49:09
	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Aug 2020 23:49:09
	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	11 Aug 2020 23:49:09
	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '11 Aug 2020 19:49'	System	11 Aug 2020 23:49:09
	System	11 Aug 2020 23:49:09

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Aug 2020 20:56'	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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	14 Aug 2020 01:07:16
	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Aug 2020 01:07:16
	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Aug 2020 01:07:16
	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '13 Aug 2020 21:07'	System	14 Aug 2020 01:07:16
	System	14 Aug 2020 01:07:16

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	15 Aug 2020 01:22:48
	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	15 Aug 2020 01:22:48
	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	15 Aug 2020 01:22:48
	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '14 Aug 2020 21:22'	System	15 Aug 2020 01:22:48
	System	15 Aug 2020 01:22:48

US3402299

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '08 Aug 2020 21:28'	System	09 Aug 2020 01:28:52
	System	09 Aug 2020 01:28:52

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '09 Aug 2020 20:38'	System	10 Aug 2020 00:38:17
	System	10 Aug 2020 00:38:17

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Aug 2020 00:29:18
	System	11 Aug 2020 00:29:18

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Aug 2020 23:50:23
	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Aug 2020 23:50:23
	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Aug 2020 23:50:23
	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Aug 2020 23:50:23
	System	11 Aug 2020 23:50:23

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Aug 2020 20:56'	System	13 Aug 2020 00:56:07
	System	13 Aug 2020 00:56:07

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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 System prevents daily activity (3)'		14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Aug 2020 01:07:57
	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Aug 2020 01:07:57
	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Aug 2020 01:07:57
	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Aug 2020 01:07:57
	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '13 Aug 2020 21:07'	System	14 Aug 2020 01:07:57
	System	14 Aug 2020 01:07:57

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	15 Aug 2020 01:23:16
	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	15 Aug 2020 01:23:16
	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	15 Aug 2020 01:23:16
	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	15 Aug 2020 01:23:16
	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	15 Aug 2020 01:23:16
	System	15 Aug 2020 01:23:16

US3402299

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '15 Aug 2020 19:22'	System	15 Aug 2020 23:22:29
	System	15 Aug 2020 23:22:29

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '16 Aug 2020 20:56'	System	17 Aug 2020 00:56:51
	System	17 Aug 2020 00:56:51

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Aug 2020 20:47:39
	System	17 Aug 2020 20:47:39

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '17 Aug 2020 16:47'	System	17 Aug 2020 20:47:39
	System	17 Aug 2020 20:47:39

US3402299

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	15 Aug 2020 23:22:41
	System	15 Aug 2020 23:22:41

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '15 Aug 2020 19:22'	System	15 Aug 2020 23:22:41
	System	15 Aug 2020 23:22:41

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	17 Aug 2020 00:56:57
	System	17 Aug 2020 00:56:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '16 Aug 2020 20:56'	System	17 Aug 2020 00:56:57
	System	17 Aug 2020 00:56:57

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	17 Aug 2020 20:47:46
	System	17 Aug 2020 20:47:46

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '17 Aug 2020 16:47'	System	17 Aug 2020 20:47:46
	System	17 Aug 2020 20:47:46

US3402299

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:02

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:02

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:02

US3402299

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:50:57
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:02

US3402299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:12:13

US3402299

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	24 Aug 2020 17:12:13

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:29

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered '22 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:29

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:29

US3402299

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:53:46
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:29

US3402299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:53:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 17:12:37

US3402299

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	24 Aug 2020 17:12:37

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:52
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:52
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:52
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:53:42

US3402299

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:52
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:53:42

US3402299

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:55
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	10 Sep 2020 15:53:48

US3402299

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:07
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:07
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:07
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: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'VISIT2'	System	10 Sep 2020 15:56:03

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'bpm'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'bpm'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:55
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: 09 Jun 2021 17:27:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	10 Sep 2020 16:26:00

US3402299

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:09
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: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:09
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: 09 Jun 2021 17:27:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered '10 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered '11:41'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4) (b) (4)	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered 'ONCE'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:56:22

US3402299

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:32
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: 09 Jun 2021 17:27:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:32
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: 09 Jun 2021 17:27:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:32
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:36
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: 09 Jun 2021 17:27:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:36
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: 09 Jun 2021 17:27:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:36
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:36
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:36
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered empty.	System	10 Sep 2020 16:26:46

US3402299

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:43
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	10 Sep 2020 16:26:51

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	10 Sep 2020 16:13:59
	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '98.1'	System	10 Sep 2020 16:13:59
	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	10 Sep 2020 16:13:59
	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 12:13'	System	10 Sep 2020 16:13:59
	System	10 Sep 2020 16:13:59

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	11 Sep 2020 02:42:44
	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '98.2'	System	11 Sep 2020 02:42:44
	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 22:42'	System	11 Sep 2020 02:42:44
	System	11 Sep 2020 02:42:44

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	11 Sep 2020 23:59:26
	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '97.6'	System	11 Sep 2020 23:59:26
	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Sep 2020 23:59:26
	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '11 Sep 2020 19:59'	System	11 Sep 2020 23:59:26
	System	11 Sep 2020 23:59:26

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Sep 2020 21:38'	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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '99.2'	System	14 Sep 2020 02:41:12
	System	14 Sep 2020 02:41:12

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	14 Sep 2020 23:42:10
	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '96.8'	System	14 Sep 2020 23:42:10
	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '14 Sep 2020 19:42'	System	14 Sep 2020 23:42:10
	System	14 Sep 2020 23:42:10

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'Yes (Y)'	System	16 Sep 2020 04:12:27
	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '97.8'	System	16 Sep 2020 04:12:27
	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	16 Sep 2020 04:12:27
	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '16 Sep 2020 00:12'	System	16 Sep 2020 04:12:27
	System	16 Sep 2020 04:12:27

US3402299

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	10 Sep 2020 16:14:16
	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	10 Sep 2020 16:14:16
	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	10 Sep 2020 16:14:16
	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	10 Sep 2020 16:14:16
	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 12:14'	System	10 Sep 2020 16:14:16
	System	10 Sep 2020 16:14:16

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 22:41'	System	11 Sep 2020 02:41:59
	System	11 Sep 2020 02:41:59

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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
	System	11 Sep 2020 23:58:41

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Sep 2020 21:37'	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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	14 Sep 2020 02:41:23
	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Sep 2020 02:41:23
	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Sep 2020 02:41:23
	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	14 Sep 2020 02:41:23
	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:23
	System	14 Sep 2020 02:41:23

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	14 Sep 2020 23:41:09
	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Sep 2020 23:41:09
	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Sep 2020 23:41:09
	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	System	14 Sep 2020 23:41:09
	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '14 Sep 2020 19:41'	System	14 Sep 2020 23:41:09
	System	14 Sep 2020 23:41:09

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	16 Sep 2020 04:11:35
	System	16 Sep 2020 04:11:35

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (1)'	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: 09 Jun 2021 17:27:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' 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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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
	System	17 Sep 2020 03:01:46

US3402299

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '16 Sep 2020 23:01'	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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 12:14'	System	10 Sep 2020 16:14:48
	System	10 Sep 2020 16:14:48

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '10 Sep 2020 22:42'	System	11 Sep 2020 02:42:19
	System	11 Sep 2020 02:42:19

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '11 Sep 2020 19:59'	System	11 Sep 2020 23:59:03
	System	11 Sep 2020 23:59:03

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '12 Sep 2020 21:38'	System	13 Sep 2020 01:38:18
	System	13 Sep 2020 01:38:18

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '13 Sep 2020 22:41'	System	14 Sep 2020 02:41:45
	System	14 Sep 2020 02:41:45

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	14 Sep 2020 23:41:35
	System	14 Sep 2020 23:41:35

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '16 Sep 2020 00:12'	System	16 Sep 2020 04:12:07
	System	16 Sep 2020 04:12:07

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Sep 2020 03:02:01
	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Sep 2020 03:02:01
	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Sep 2020 03:02:01
	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Sep 2020 03:02:01
	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'None (0)'	System	17 Sep 2020 03:02:01
	System	17 Sep 2020 03:02:01

US3402299

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:26
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: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:26
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:26
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: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:26
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:31
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	17 Sep 2020 18:55:50

US3402299

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:43
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:43
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:43
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: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:43
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:55:47
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	24 Sep 2020 14:57:24

US3402299

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
Query 'Unable to find in source. Please add to source for SDV. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:18
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:31:12
User opened query 'Unable to find in source. Please add to source for SDV. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 20:57:54
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 20:57:27
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:56:03
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: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:55
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
User closed query 'Per source this was completed on 01Oct2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4)	22 Feb 2021 05:12:17
Query 'Per source this was completed on 01Oct2020. Please verify and update accordingly. ' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	15 Feb 2021 20:15:53
DataPoint Un-verified.	(b) (4)	15 Feb 2021 20:15:46
User entered '01 Oct 2020' reason for change: New Information	Tammy Kohn (b) (4)	15 Feb 2021 20:15:46
User opened query 'Per source this was completed on 01Oct2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:31:50
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 20:57:28
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:56:03
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 20:57:30
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:56:03
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: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 20:57:31
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:56:03
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:49:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:32:00
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	05 Oct 2020 20:14:24

US3402299

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:10
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:10
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:10
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: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'VISIT3'	System	15 Oct 2020 20:18:54

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'bpm'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'breaths/min'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:28
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) (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) (b) (4)	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'mmHg'	System	15 Oct 2020 20:19:27

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19

US3402299

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19

US3402299

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:35
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: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:35
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: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:39
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: 09 Jun 2021 17:27:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:39
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: 09 Jun 2021 17:27:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:39
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:58:45
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered '1'	System	15 Oct 2020 20:22:56

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 64'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '08 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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '12 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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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'	System	22 Oct 2020 10:19:32
User entered 'No (N)'	System	22 Oct 2020 10:19:32

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered '05 Nov 2020 16:14:46'	System	05 Nov 2020 21:14:48
	System	05 Nov 2020 21:14:48

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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' User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:11
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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered 'Day 106'	System	08 Aug 2020 18:24:04

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57

US3402299

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '19 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: 09 Jun 2021 17:27:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:39:57
Data entry locked.	System	08 Aug 2020 18:24:04
User entered '23 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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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' 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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2020-11-30T06:15:43', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4b50f377-efcc-40cd-bc57-51ca189f474a' User entered 'No (N)'	System	30 Nov 2020 11:15:58
	System	30 Nov 2020 11:15:58

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2020-11-30T06:15:49', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4b50f377-efcc-40cd-bc57-51ca189f474a' User entered 'No (N)'	System	30 Nov 2020 11:15:58

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-11-30T06:15:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4b50f377-efcc-40cd-bc57-51ca189f474a' User entered '30 Nov 2020 06:15:53'	System	30 Nov 2020 11:15:58
	System	30 Nov 2020 11:15:58

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2020-12-10T20:00:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9acea52f-2e02-4db6-94dd-6b3dd5bbd15a' User entered 'No (N)'	System	11 Dec 2020 01:01:04
	System	11 Dec 2020 01:01:04

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2020-12-10T20:00:57', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9acea52f-2e02-4db6-94dd-6b3dd5bbd15a' User entered 'No (N)'	System	11 Dec 2020 01:01:04
	System	11 Dec 2020 01:01:04

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-10T20:01:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9acea52f-2e02-4db6-94dd-6b3dd5bbd15a' User entered '10 Dec 2020 20:01:00'	System	11 Dec 2020 01:01:04
	System	11 Dec 2020 01:01:04

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2020-12-16T13:53:23', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '31e317a7-67fb-46a7-8b7d-832a0adc7e16' User entered 'No (N)'	System	16 Dec 2020 18:53:32
	System	16 Dec 2020 18:53:32

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-16T13:53:25', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '31e317a7-67fb-46a7-8b7d-832a0adc7e16' User entered 'No (N)'	System	16 Dec 2020 18:53:32
	System	16 Dec 2020 18:53:32

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-16T13:53:28', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '31e317a7-67fb-46a7-8b7d-832a0adc7e16' User entered '16 Dec 2020 13:53:28'	System	16 Dec 2020 18:53:32
	System	16 Dec 2020 18:53:32

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2020-12-21T06:00:28', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '737a0a68-cf81-4c49-aca6-45f5136e7c96'	System	21 Dec 2020 11:00:35
User entered 'No (N)'	System	21 Dec 2020 11:00:35

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-21T06:00:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '737a0a68-cf81-4c49-aca6-45f5136e7c96'	System	21 Dec 2020 11:00:35
User entered 'No (N)'	System	21 Dec 2020 11:00:35

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-21T06:00:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '737a0a68-cf81-4c49-aca6-45f5136e7c96' User entered '21 Dec 2020 06:00:33'	System	21 Dec 2020 11:00:35
	System	21 Dec 2020 11:00:35

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2020-12-28T07:27:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4c9b5cef-d2e8-45fa-a6a0-dd4de9bee300' User entered 'No (N)'	System	28 Dec 2020 12:27:42
	System	28 Dec 2020 12:27:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2020-12-28T07:27:35', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4c9b5cef-d2e8-45fa-a6a0-dd4de9bee300'	System	28 Dec 2020 12:27:42
User entered 'No (N)'	System	28 Dec 2020 12:27:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2020-12-28T07:27:39', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '4c9b5cef-d2e8-45fa-a6a0-dd4de9bee300' User entered '28 Dec 2020 07:27:39'	System	28 Dec 2020 12:27:42
	System	28 Dec 2020 12:27:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-01-04T20:21:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9c13b590-9935-470d-a4c2-dafe17ba9d99'	System	05 Jan 2021 01:21:20
User entered 'No (N)'	System	05 Jan 2021 01:21:20

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-01-04T20:21:12', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9c13b590-9935-470d-a4c2-dafe17ba9d99'	System	05 Jan 2021 01:21:20
User entered 'No (N)'	System	05 Jan 2021 01:21:20

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-04T20:21:15', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9c13b590-9935-470d-a4c2-dafe17ba9d99' User entered '04 Jan 2021 20:21:15'	System	05 Jan 2021 01:21:20
	System	05 Jan 2021 01:21:20

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-01-11T06:00:31', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbb28d36-2818-421d-9a1d-74826a07ff50'	System	11 Jan 2021 11:00:40
User entered 'No (N)'	System	11 Jan 2021 11:00:40

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-01-11T06:00:34', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbb28d36-2818-421d-9a1d-74826a07ff50'	System	11 Jan 2021 11:00:40
User entered 'No (N)'	System	11 Jan 2021 11:00:40

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-11T06:00:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbb28d36-2818-421d-9a1d-74826a07ff50' User entered '11 Jan 2021 06:00:37'	System	11 Jan 2021 11:00:40
	System	11 Jan 2021 11:00:40

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-01-19T07:19:32', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbf56ab0-bcd8-4ac5-800a-2db952563ccb' User entered 'No (N)'	System	19 Jan 2021 12:19:42
	System	19 Jan 2021 12:19:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-19T07:19:37', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbf56ab0-bcd8-4ac5-800a-2db952563ccb' User entered 'No (N)'	System	19 Jan 2021 12:19:42
	System	19 Jan 2021 12:19:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-19T07:19:40', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'dbf56ab0-bcd8-4ac5-800a-2db952563ccb' User entered '19 Jan 2021 07:19:40'	System	19 Jan 2021 12:19:42
	System	19 Jan 2021 12:19:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-01-25T12:41:10', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b06cb0-d744-4509-9ebe-62f0eda7f23c' User entered 'No (N)'	System	25 Jan 2021 17:41:26

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-25T12:41:18', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b06cb0-d744-4509-9ebe-62f0eda7f23c' User entered 'No (N)'	System	25 Jan 2021 17:41:26

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-01-25T12:41:21', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b06cb0-d744-4509-9ebe-62f0eda7f23c' User entered '25 Jan 2021 12:41:21'	System	25 Jan 2021 17:41:26

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-02-02T15:09:53', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b0c713-cf84-4a19-bca4-17997b0ca137' User entered 'No (N)'	System	02 Feb 2021 20:10:08
	System	02 Feb 2021 20:10:08

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-02-02T15:10:02', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b0c713-cf84-4a19-bca4-17997b0ca137' User entered 'No (N)'	System	02 Feb 2021 20:10:08
	System	02 Feb 2021 20:10:08

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-02-02T15:10:05', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '47b0c713-cf84-4a19-bca4-17997b0ca137' User entered '02 Feb 2021 15:10:05'	System	02 Feb 2021 20:10:08
	System	02 Feb 2021 20:10:08

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-02-08T22:19:44', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0a45ab5a-328b-4388-b32d-e956c1e1fb5b' User entered 'No (N)'	System	09 Feb 2021 03:19:52
	System	09 Feb 2021 03:19:52

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-02-08T22:19:47', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0a45ab5a-328b-4388-b32d-e956c1e1fb5b' User entered 'No (N)'	System	09 Feb 2021 03:19:52
	System	09 Feb 2021 03:19:52

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-02-08T22:19:50', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '0a45ab5a-328b-4388-b32d-e956c1e1fb5b' User entered '08 Feb 2021 22:19:50'	System	09 Feb 2021 03:19:52
	System	09 Feb 2021 03:19:52

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-02-15T06:17:56', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'da6b3b7f-8250-406e-82d0-5f2ab0b4e937'	System	15 Feb 2021 11:18:56
User entered 'No (N)'	System	15 Feb 2021 11:18:56

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-02-15T06:18:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'da6b3b7f-8250-406e-82d0-5f2ab0b4e937'	System	15 Feb 2021 11:18:56
User entered 'No (N)'	System	15 Feb 2021 11:18:56

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-02-15T06:18:54', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'da6b3b7f-8250-406e-82d0-5f2ab0b4e937' User entered '15 Feb 2021 06:18:54'	System	15 Feb 2021 11:18:56
	System	15 Feb 2021 11:18:56

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-02-22T06:15:23', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7d1036e1-60e1-47ae-8bdf-77ab7fab6fbf' User entered 'No (N)'	System	22 Feb 2021 11:15:38
	System	22 Feb 2021 11:15:38

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-02-22T06:15:29', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7d1036e1-60e1-47ae-8bdf-77ab7fab6fbf' User entered 'No (N)'	System	22 Feb 2021 11:15:38
	System	22 Feb 2021 11:15:38

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-02-22T06:15:33', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7d1036e1-60e1-47ae-8bdf-77ab7fab6fbf' User entered '22 Feb 2021 06:15:33'	System	22 Feb 2021 11:15:38
	System	22 Feb 2021 11:15:38

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-03-01T06:17:42-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5a249cf7-95af-4b22-856d-a5c57d68f98e' User entered 'No (N)'	System	01 Mar 2021 11:17:53
	System	01 Mar 2021 11:17:53

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-03-01T06:17:46-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5a249cf7-95af-4b22-856d-a5c57d68f98e'	System	01 Mar 2021 11:17:53
User entered 'No (N)'	System	01 Mar 2021 11:17:53

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-01T06:17:49-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '5a249cf7-95af-4b22-856d-a5c57d68f98e' User entered '01 Mar 2021 06:17:49'	System	01 Mar 2021 11:17:53
	System	01 Mar 2021 11:17:53

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-03-08T17:19:10-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7adc1f7c-1043-4a25-83df-ccd4d42ceab4'	System	08 Mar 2021 22:58:10
User entered 'No (N)'	System	08 Mar 2021 22:58:10

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-03-08T17:19:14-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7adc1f7c-1043-4a25-83df-ccd4d42ceab4'	System	08 Mar 2021 22:58:10
User entered 'No (N)'	System	08 Mar 2021 22:58:10

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-08T17:19:16-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '7adc1f7c-1043-4a25-83df-ccd4d42ceab4'	System	08 Mar 2021 22:58:10
User entered '08 Mar 2021 17:19:16'	System	08 Mar 2021 22:58:10

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-03-15T07:30:51-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8ea90f7-87c0-414a-a25f-f055f032d321' User entered 'No (N)'	System	15 Mar 2021 11:30:59
	System	15 Mar 2021 11:30:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-03-15T07:30:53-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8ea90f7-87c0-414a-a25f-f055f032d321'	System	15 Mar 2021 11:30:59
User entered 'No (N)'	System	15 Mar 2021 11:30:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-15T07:30:56-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'a8ea90f7-87c0-414a-a25f-f055f032d321' User entered '15 Mar 2021 07:30:56'	System	15 Mar 2021 11:30:59

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-03-22T06:15:41-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '853a4393-3169-48eb-9d49-9df8018a879d' User entered 'No (N)'	System	22 Mar 2021 10:15:51
	System	22 Mar 2021 10:15:51

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-03-22T06:15:43-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '853a4393-3169-48eb-9d49-9df8018a879d' User entered 'No (N)'	System	22 Mar 2021 10:15:51
	System	22 Mar 2021 10:15:51

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-22T06:15:46-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '853a4393-3169-48eb-9d49-9df8018a879d'	System	22 Mar 2021 10:15:51
User entered '22 Mar 2021 06:15:46'	System	22 Mar 2021 10:15:51

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-03-29T08:22:34-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b683a52b-4bee-4dcf-a5bc-81559a292231' User entered 'No (N)'	System	29 Mar 2021 12:22:44
	System	29 Mar 2021 12:22:44

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-29T08:22:38-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b683a52b-4bee-4dcf-a5bc-81559a292231'	System	29 Mar 2021 12:22:44
User entered 'No (N)'	System	29 Mar 2021 12:22:44

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-03-29T08:22:41-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'b683a52b-4bee-4dcf-a5bc-81559a292231' User entered '29 Mar 2021 08:22:41'	System	29 Mar 2021 12:22:44
	System	29 Mar 2021 12:22:44

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-04-05T20:14:48-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c6296c48-3a0c-4fd5-9c1c-5fa26261c9ba' User entered 'No (N)'	System	06 Apr 2021 00:14:57
	System	06 Apr 2021 00:14:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-04-05T20:14:52-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c6296c48-3a0c-4fd5-9c1c-5fa26261c9ba' User entered 'No (N)'	System	06 Apr 2021 00:14:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-04-05T20:14:55-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'c6296c48-3a0c-4fd5-9c1c-5fa26261c9ba' User entered '05 Apr 2021 20:14:55'	System	06 Apr 2021 00:14:57
	System	06 Apr 2021 00:14:57

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-04-12T06:06:34-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '343ea2f5-79ae-40a8-b1a3-5872dfbba27a' User entered 'No (N)'	System	12 Apr 2021 10:06:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-04-12T06:06:35-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '343ea2f5-79ae-40a8-b1a3-5872dfbba27a' User entered 'No (N)'	System	12 Apr 2021 10:06:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-04-12T06:06:39-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '343ea2f5-79ae-40a8-b1a3-5872dfbba27a' User entered '12 Apr 2021 06:06:39'	System	12 Apr 2021 10:06:42
	System	12 Apr 2021 10:06:42

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-04-19T18:19:33-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'af29f7c3-2fbb-4641-9527-ca3bd9dc2673' User entered 'No (N)'	System	19 Apr 2021 22:19:41

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-04-19T18:19:35-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'af29f7c3-2fbb-4641-9527-ca3bd9dc2673'	System	19 Apr 2021 22:19:41
User entered 'No (N)'	System	19 Apr 2021 22:19:41

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-04-19T18:19:37-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: 'af29f7c3-2fbb-4641-9527-ca3bd9dc2673'	System	19 Apr 2021 22:19:41
User entered '19 Apr 2021 18:19:37'	System	19 Apr 2021 22:19:41

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-04-27T07:07:06-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '813f474e-9fcc-4bbc-9eca-47ffd88478e8' User entered 'No (N)'	System	28 Apr 2021 22:40:39

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-04-27T07:07:07-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '813f474e-9fcc-4bbc-9eca-47ffd88478e8'	System	28 Apr 2021 22:40:39
User entered 'No (N)'	System	28 Apr 2021 22:40:39

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-04-27T07:07:10-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '813f474e-9fcc-4bbc-9eca-47ffd88478e8' User entered '27 Apr 2021 07:07:10'	System	28 Apr 2021 22:40:39
	System	28 Apr 2021 22:40:39

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: '2021-05-03T19:54:18-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9a004bac-dbc4-4436-b8c6-923182051221' User entered 'No (N)'	System	03 May 2021 23:54:25
	System	03 May 2021 23:54:25

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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: '2021-05-03T19:54:20-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9a004bac-dbc4-4436-b8c6-923182051221'	System	03 May 2021 23:54:25
User entered 'No (N)'	System	03 May 2021 23:54:25

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: '2021-05-03T19:54:23-04:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '9a004bac-dbc4-4436-b8c6-923182051221' User entered '03 May 2021 19:54:23'	System	03 May 2021 23:54:25
	System	03 May 2021 23:54:25

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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

US3402299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2021-02-27T18:08:54-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '8e42cb4f-9200-4ffe-8f47-012e622d7920' User entered 'No (N)'	System	27 Feb 2021 23:11:25
	System	27 Feb 2021 23:11:25

US3402299

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F47E5658-2AE2-4AAE-A521-7C7EF152A051)', Time: '2021-02-27T18:08:57-05:00', User OID: 'PatientReportedOutcome (US3402299)', ODM File OID: '8e42cb4f-9200-4ffe-8f47-012e622d7920' User entered '27 Feb 2021 23:08:57'	System	27 Feb 2021 23:11:25
	System	27 Feb 2021 23:11:25

US3402299

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:27
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: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:27
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:27
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: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:27
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:31
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: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:19
User entered 'I'	System	06 Nov 2020 14:43:26

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:18:00
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Dec 2020 15:45:19

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:18:00
User entered '9 Dec 2020'	Traci Hull (b) (4) (b) (4)	09 Dec 2020 15:45:19

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:18:00
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	09 Dec 2020 15:45:19

US3402299

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:18:00
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Dec 2020 15:45:19

US3402299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:18:06
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Dec 2020 15:45:25

US3402299

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User entered 'I'	System	09 Dec 2020 15:45:25

US3402299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:58
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 15:59:40

US3402299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:58
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 15:59:40

US3402299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:58
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 15:59:40

US3402299

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:59:58
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Jan 2021 15:59:40

US3402299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:00:05
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 15:59:26

US3402299

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User entered 'I'	System	07 Jan 2021 15:59:26

US3402299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:07
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 19:52:23

US3402299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:07
User entered '4 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 19:52:23

US3402299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:07
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 19:52:23

US3402299

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:07
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Feb 2021 19:52:23

US3402299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:10
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 19:52:26

US3402299

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:54
User entered 'I'	System	05 Feb 2021 19:52:26

US3402299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:23
User closed query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:07:01
Query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you. ' answered with 'No Vitals to be entered' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	31 Mar 2021 13:44:53
User opened query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:42:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:17

US3402299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:23
User entered '11 Mar 2021'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:17

US3402299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:23
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:17

US3402299

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered 'VISIT4'	System	11 Mar 2021 21:07:17

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered empty.	System	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered empty.	System	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered empty.	System	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered empty.	System	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:37
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered empty.	System	31 Mar 2021 13:30:29

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32

US3402299

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32

US3402299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:54
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:21

US3402299

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:25:54
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:21

US3402299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:01
Comment added 'OL-3 KIT USED PER PROTOCOL AS BOTH VISITS WERE DONE AT SAME TIME'.	Traci Hull (b) (4)	11 Mar 2021 21:08:34
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:35

US3402299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:01
User entered '11 Mar 2021'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:35

US3402299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:01
User entered '15:05'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:35

US3402299

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered '11 Mar 2021 15:05'	System	11 Mar 2021 21:07:35

US3402299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:11
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:07:40

US3402299

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:50:32
User entered 'I'	System	11 Mar 2021 21:07:40

US3402299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Apr 2021 13:32:36
	(b) (4)	

US3402299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered '7 Apr 2021'	Traci Hull (b) (4)	07 Apr 2021 13:32:36
	(b) (4)	

US3402299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	07 Apr 2021 13:32:36

US3402299

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	07 Apr 2021 13:32:36
	(b) (4)	

US3402299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Apr 2021 13:32:40
	(b) (4)	

US3402299

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 13:32:40

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:06
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:32:53

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:06
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:32:53

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:06
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:32:53

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:32:53

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered '06 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered '0'	Tammy Kohn (b) (4)	08 Apr 2021 20:23:12
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:59:46

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:34:22
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 20:23:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 20:23:12
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:52:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:59:46

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:47:09
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:47:09
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:19:17
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '1'	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	14 Jan 2021 21:35:34
DataPoint set to visible.	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	14 Jan 2021 21:35:34
DataPoint set to visible.	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '14:37'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '14 Jan 2021 14:37'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '36.7' C	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered empty.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '64'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'bpm'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '16'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'breaths/min'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '120'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
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).	System	14 Jan 2021 21:36:12
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 by data change (Site from System).	System	14 Jan 2021 21:36:12
User entered '68' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:36:12
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	14 Jan 2021 21:35:34
User entered '58'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	14 Jan 2021 21:35:34
DataPoint set to visible.	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '15:32'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '14 Jan 2021 15:32'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '36.6' C	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered empty.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '66'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'bpm'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '16'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'breaths/min'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '122'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:02
User entered '62'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	14 Jan 2021 21:35:34

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:10
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:36:28

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:10
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:36:28

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18
	(b) (4)	

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18
	(b) (4)	

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:40:31
User entered empty.	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mRNA-1273'	System	14 Jan 2021 21:37:18
DataPoint set to visible.	System	14 Jan 2021 21:33:17

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14 Jan 2021'	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18
	(b) (4)	

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:40:31
User entered '15:00'	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '14 Jan 2021 15:00'	System	14 Jan 2021 21:37:18

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4)	14 Jan 2021 21:37:18
	(b) (4)	

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:40:31
User entered 'ONCE'	System	14 Jan 2021 21:37:18

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 21:37:18

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:18
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:36

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:18
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:36

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:18
User entered '14:29'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:36

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '14 Jan 2021 14:29'	System	14 Jan 2021 21:33:36

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:23
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:48

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:23
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:48

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:23
User entered '14:26'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:48

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '14 Jan 2021 14:26'	System	14 Jan 2021 21:33:48

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:27
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 21:33:54

US3402299

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	14 Jan 2021 21:33:54

US3402299

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:54
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	11 Feb 2021 14:48:05

US3402299

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:54
User entered '21 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	11 Feb 2021 14:48:05

US3402299

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:54
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	11 Feb 2021 14:48:05

US3402299

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:54
User entered empty.	Tammy Kohn (b) (4) (b) (4)	11 Feb 2021 14:48:05

US3402299

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:20:59
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	11 Feb 2021 14:48:09

US3402299

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	11 Feb 2021 14:48:09

US3402299

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	11 Feb 2021 14:48:09
DataPoint set to visible.	System	11 Feb 2021 14:48:09

US3402299

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:21:37
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:41:38

US3402299

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:21:37
User entered '11 Feb 2021'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:41:38

US3402299

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:21:37
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:41:38

US3402299

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'OLD29'	System	11 Feb 2021 20:41:38

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '11 Feb 2021'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '14:24'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '11 Feb 2021 14:24'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '64'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'bpm'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '16'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'breaths/min'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '118'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '62'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '11 Feb 2021'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '15:30'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '11 Feb 2021 15:30'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '66'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'bpm'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '16'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'breaths/min'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '120'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:29
User entered '64'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mmHg'	System	11 Feb 2021 20:42:57

US3402299

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:42
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:04

US3402299

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:42
User entered '11 Feb 2021'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:04

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered empty.	Traci Hull (b) (4)	11 Feb 2021 20:43:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'mRNA-1273'	System	11 Feb 2021 20:43:22
DataPoint set to visible.	System	11 Feb 2021 14:48:09

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered '11 Feb 2021'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered '14:57'	Traci Hull (b) (4)	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '11 Feb 2021 14:57'	System	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:14
User entered 'ONCE'	System	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 20:43:22

US3402299

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:23:59
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Feb 2021 20:43:26

US3402299

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	11 Feb 2021 20:43:26

US3402299

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:17
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 21:04:30

US3402299

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:17
User entered '18 Feb 2021'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 21:04:30

US3402299

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:17
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 21:04:30

US3402299

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:17
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Feb 2021 21:04:30

US3402299

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 21:04:16

US3402299

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'I'	System	18 Feb 2021 21:04:16

US3402299

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:37
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:08:55

US3402299

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:37
User entered '11 Mar 2021'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:08:55

US3402299

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:37
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:08:55

US3402299

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered 'OLD57'	System	11 Mar 2021 21:08:55

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:46
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered empty.	System	11 Mar 2021 21:09:08

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43

US3402299

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43

US3402299

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:52
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:16

US3402299

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:52
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:16

US3402299

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:02
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:29

US3402299

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:02
User entered '11 Mar 2021'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:29

US3402299

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:27:02
User entered '15:05'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 21:09:29

US3402299

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:43
User entered '11 Mar 2021 15:05'	System	11 Mar 2021 21:09:29

US3402299

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:47
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
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) (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: 09 Jun 2021 17:27:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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	System	04 Sep 2020 17:05:13
'USA-US059-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	04 Sep 2020 17:05:13

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: 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

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please remove planned elective procedure as event and consider adding SAE of postoperative bleeding. ' answered with 'updated' (Site from Safety). Coding entries removed.	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:27:55
User entered 'Post Operative bleeding' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	(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)	(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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'ABDOMINAL PANNUS'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '01 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '4'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	03 Sep 2020 10:49:16

US3402299

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:06:36
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 14:47:23
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'DATA U PDATED' (Site from Safety).	Tammy Kohn (b) (4)	04 Dec 2020 16:09:40
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	04 Dec 2020 16:09:01
	(b) (4)	
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	04 Dec 2020 16:09:01
	(b) (4)	
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:25:36
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'I'	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: 09 Jun 2021 17:27:25

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:29:09
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'ALL THERAPEUTIC PROCEDURES ARE RECORDED FROM 26 AUG TO 28 AUG 2020' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Jan 2021 21:42:52
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:46:06
User closed query 'Please check this box as Con Procedures were noted in source. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 13:26:56
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 13:26:53
Query 'Please check this box as Con Procedures were noted in source. ' answered with 'updated ' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	25 Nov 2020 03:31:12
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	25 Nov 2020 03:29:36
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 09 Jun 2021 17:27:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:32:47
User entered empty.	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: 09 Jun 2021 17:27:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
User closed query 'PV Query: Please provide the date when the subject received the second dose of study drug, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:46:23
Query 'PV Query: Please provide the date when the subject received the second dose of study drug, when available.' answered with '2ND DOSE ADMINISTERED ON 10SEP2020' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 18:48:12
User opened query 'PV Query: Please provide the date when the subject received the second dose of study drug, when available.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:34:22
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Narrative](#)

Audit	User	Time (GMT)
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)	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)	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)	02 Oct 2020 17:05:32
Query 'PV Query: Since the subject had abdominal pannus prior to enrolling in the study, please consider adding abdominal pannus as medical history.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	02 Oct 2020 17:04:45
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. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 13:06:57
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

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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
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)	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)	11 Sep 2020 20:13:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider adding abdominal pannus as medical history. ' (Site from Safety).	(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)	11 Sep 2020 20:11:14
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.	Jennifer Molstead (b) (4)	03 Sep 2020 10:49:16
Subject also had a CT Angiography of the chest to rule out pulmonary embolism. No Pulmonary Emboli were found. Chest X-Ray 29Aug2020 Normal. Abdominal X-Ray Normal. After significant recovery patient was discharged 01Sep2020.'		

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 10:49:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:09:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:09:50
Data point term sent to Coder	System	10 Nov 2020 00:08:13
User entered 'SEVERE HEADACHE'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '11 Aug 2020'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User entered empty.	System	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '16 Aug 2020'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User entered empty.	System	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Related (RELATED)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Not Related (NOT RELATED)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'None (NONE)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'l'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:44:05
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User entered '0'	System	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37
User entered '0'	System	10 Nov 2020 00:07:47

US3402299

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:38:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:47
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '150'	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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
User entered 'UN UNK 2016'	System	08 Aug 2020 21:48:59
	Traci Hull (b) (4)	08 Aug 2020 21:48:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 21:48:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	08 Aug 2020 21:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
User entered 'UN UNK 2010'	System	08 Aug 2020 21:49:31
	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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	08 Aug 2020 21:49:31

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
User entered 'UN UNK 2008'	System	08 Aug 2020 21:50:05
	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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	10 Aug 2020 13:08:44
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	10 Aug 2020 13:08:44
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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) (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) (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) (b) (4)	10 Aug 2020 13:09:20

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (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)	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)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'I'	Traci Hull (b) (4)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
User entered 'UN UNK 2010'	System	10 Aug 2020 13:11:17
	Traci Hull (b) (4)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	10 Aug 2020 13:11:17
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	10 Aug 2020 13:12:46
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	10 Aug 2020 13:12:46
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 13:12:46
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	10 Aug 2020 13:13:28
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'CONSTITUTION'	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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '24'	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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'once daily (QD)'	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: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	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: 09 Jun 2021 17:27:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
User entered 'UN UNK 2011'	System	10 Aug 2020 13:13:28
	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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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) (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.	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 19:24:16
' answered with 'NO WORSENING OF MIGRAINE HEADACHES. PATIENT HAD ISSUES PRIOR TO BEGINNING OF STUDY.' (Site from DM).		
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) (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) (b) (4)	24 Aug 2020 17:15:35
Data point term sent to Coder	System	24 Aug 2020 17:14:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'IBUPROFEN'	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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'MIGRAINE HEADACHES'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '400'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mg (mg)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'as needed (PRN)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	
User entered '14 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'No (N)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '15 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:14:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:22
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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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)	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)	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)	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)	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)	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)	03 Sep 2020 10:53:09

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:26
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: 09 Jun 2021 17:27:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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)	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)	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)	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)	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)	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)	03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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)	12 Oct 2020 17:55:28
DataPoint Un-verified.	Tammy Kohn (b) (4)	12 Oct 2020 17:52:40
User entered 'IDIOPATHIC ABDOMINAL PANNUS' reason for change: Data Entry Error	Tammy Kohn (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)	05 Oct 2020 16:56:15

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
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). User entered 'Abdominal Pannus'	(b) (4), (b) (6) (b) (4) Jennifer Molstead (b) (4)	02 Oct 2020 04:44:40 03 Sep 2020 10:54:30

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	
User entered '26 Aug 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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:30
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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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) (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: 09 Jun 2021 17:27:25

[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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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
	(b) (4)	
User entered 'Abdominal Pannus'	Jennifer Molstead (b) (4)	03 Sep 2020 10:57:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:36
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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Yes (Y)'	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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered '0.5'	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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'mL (mL)'	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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:35:02
User entered empty.	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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:39
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: 09 Jun 2021 17:27:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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)	30 Dec 2020 21:15:21
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 21:15:21
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 19:42:38
Coding entries removed.	Tammy Kohn (b) (4)	30 Dec 2020 19:42:33
	(b) (4)	
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)	12 Nov 2020 14:57:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 14:57:47
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 14:56:11
User entered 'ibuprofen'	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: 09 Jun 2021 17:27:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:33:43
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 10:51:28
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'DATA UPDATED NO AE OR SAE AS THIS IS WITHIN THE 7 DAYS AFTER INJECTION' (Site from DM).	Tammy Kohn (b) (4)	30 Dec 2020 19:42:58
DataPoint Un-verified.	Tammy Kohn (b) (4)	30 Dec 2020 19:42:33
User entered 'HEADACHE AFTER INJECTION' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Dec 2020 19:42:33

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	30 Dec 2020 05:31:12
	(b) (4), (b) (6) (b) (4)	23 Nov 2020 21:24:31
User entered 'headache'	Tarin Gordon (b) (4) (b) (4)	12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
	(b) (4)	
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:45
User entered empty.	System	12 Nov 2020 14:55:35

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:27:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:47
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
User closed 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) (4), (b) (6)	21 Dec 2020 18:23:39
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' answered with 'DATA HAS BEEN ADDED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 19:41:11
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) (b) (4)	24 Nov 2020 17:15:51

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:27:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	24 Nov 2020 17:15:51
DataPoint Verified.	(b) (4)	
	(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: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '26 Aug 2020'	Tammy Kohn (b) (4)	25 Nov 2020 15:58:32
	(b) (4)	

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'PANNICULECTOMY'	Tammy Kohn (b) (4)	25 Nov 2020 15:58:32
	(b) (4)	

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Other (OTHER)'	Tammy Kohn (b) (4)	25 Nov 2020 15:58:32
	(b) (4)	

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'PLANNED PROCEDURE'	Tammy Kohn (b) (4)	25 Nov 2020 15:58:32
	(b) (4)	

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:56
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '27 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 15:59:21

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:56
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'COMPLETE BLOOD COUNT'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 15:59:21

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:56
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 15:59:21

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:56
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 15:59:21

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '27 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:04

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'CT ANGROGRAPHY'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:04

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:04

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:04

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '27 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:37

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'CT ABDOMEN'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:37

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:37

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:00:37

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '27 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'CT PELVIS'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
User closed query 'Per source - Chest X-Ray was performed on 27 Aug 2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:11
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:09
Query 'Per source - Chest X-Ray was performed on 27 Aug 2020. Please verify and update accordingly. ' answered with 'data corrected' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	21 Dec 2020 18:49:14
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Dec 2020 18:49:09
User entered '27 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Dec 2020 18:49:09
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:23:32
User opened query 'Per source - Chest X-Ray was performed on 27 Aug 2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:23:29
User entered '29 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:27

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'CHEST XRAY'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:27

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:27

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:01:27

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:27:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:07
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered '28 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:02:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:27:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:07
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'POST OPERATIVE BLEEDING'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:02:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:27:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:07
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:02:02

US3402299

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:27:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:07
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:23:32
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Nov 2020 16:02:02

US3402299

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

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 12:46:42
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 05:10:01
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 14:13:15

US3402299

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

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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 (4)

Generated On: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:59:55
User entered '25/Nov/2020 12:46'	System	25 Nov 2020 12:46:54

US3402299

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

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:59:57
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 12:46:54

US3402299

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

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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 (5)

Generated On: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:00:04
User entered '07/Dec/2020 09:49'	System	07 Dec 2020 14:49:16

US3402299

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

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:00:28
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 14:49:16

US3402299

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

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:27:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:27:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Dec 2020 16:46:57
User entered '5'	System	07 Dec 2020 14:49:16
User entered '4'	System	25 Nov 2020 12:46:54
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 (6)

Generated On: 09 Jun 2021 17:27:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:00:35
User entered '21/Dec/2020 10:46'	System	21 Dec 2020 16:46:57

US3402299

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

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:27:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:00:37
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 16:46:57